UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	)	MD 15-02641-PHX-DGC
Lisa Hyde and Mark Hyde, a married couple,	)	Phoenix, Arizona **September 18, 2018**
Plaintiffs,	)	
v.	)	CV 16-00893-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation, and Bard Peripheral Vascular, an Arizona corporation,	)	
Defendants.	)	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 1 - P.M. SESSION

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Proceedings Reported by Stenographic Court Reporter
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I N D E X

P R O C E E D I N G S

(Proceedings resumed at 1:29 p.m.)

(Jury present.)

THE COURT: All right, ladies and gentlemen, welcome back.

As indicated, I'm going to now give you some preliminary jury instructions. And these instructions primarily will function -- or focus on some general instructions about the law and how the trial is going to proceed and your duty as jurors.

It is your duty as jurors to find the facts from all of the evidence in the case. To those facts as you find them, you will apply the law as I give it to you. And I will give it to you in instructions at the end of the trial.

You must follow the law as I give it to you, whether you agree with it or not, and you must not be influenced in your decision by any personal likes or dislikes, opinions, prejudices, or sympathy. That means that you must decide the case solely on the evidence before you and the law as I give it to you. You will recall that you took an oath to do so.

As I mentioned, at the end of the trial I will give you final jury instructions. It is those final instructions that will govern your deliberation in the case.

Please do not read into my instructions or anything I may say or do during the trial as indicating any opinion I have

of the evidence or of what your verdict should be. The verdict is entirely a matter for you to decide.

To help you follow the evidence, I will give you a brief summary of the positions of the parties.

This is a personal injury case against a medical product manufacturer. The plaintiffs are Lisa Hyde and her husband, Mark Hyde. Mrs. Hyde is a 54-year-old woman who had a Bard filter placed in her inferior vena cava, the vein that carries blood back to the heart. An IVC filter, as it is called, is intended to catch blood clots before they reach the heart or lungs.

Defendants, C.R. Bard Inc. and Bard Peripheral Vascular, designed, manufactured, and sold the Bard filter.

Plaintiffs claim that the Bard filter was defectively and negligently designed. They allege that Mrs. Hyde was injured by the filter, and they seek to recover money from defendants to compensate for her injuries and for Mr. Hyde's loss of consortium. Plaintiffs also seek damages to punish defendants for their allegedly wrongful conduct.

Defendants deny that they are liable or that the filter was defectively or negligently designed. Defendants assert that they are not responsible for any injuries or damages suffered by plaintiffs.

Although there are two defendants in this case, C.R. Bard Inc. and Bard Peripheral Vascular Inc., you should

decide the case as to the two defendants jointly. As a result, in these instructions and often in my comments during trial and the lawyers' comments, we will refer to the defendants collectively as "Bard."

Unless otherwise stated, the instructions that I give you apply to both Bard and the plaintiffs.

The evidence that you will consider in deciding what the facts are consists of the sworn testimony of the witnesses that you will hear, the exhibits that are admitted into evidence, any facts to which the lawyers have agreed -- and if they have agreed on facts, that will be made clear to you -- and any facts that I may instruct you to accept as proved.

In reaching your verdict, you may consider only the testimony and the exhibits received in the evidence and the facts to which the parties have agreed. Certain things are not evidence, and you may not consider them in deciding what the facts are. I will list them for you.

First, arguments and statements by lawyers are not evidence. The lawyers are not witnesses. What they may say in their opening statements, closing arguments, and at other times is intended to help you interpret the evidence, but it is not evidence. If the facts as you find them differ from the way the lawyers have stated them, your finding of the facts controls.

Second, questions and objections by lawyers are not

evidence. Attorneys have a duty to their clients to object when they believe a question is improper under the rules of evidence. You should not be influenced by the objection of a lawyer or by my ruling on it.

Third, any testimony that is excluded or stricken by me or that I instruct you to disregard is not evidence and must not be considered. In addition, some evidence may be received only for a limited purpose, and if it is, I will instruct you that it is being received for a limited purpose. When I instruct you to consider certain evidence only for a limited purpose, you must do so, and you may not consider that evidence for any other purpose.

Fourth, anything you may see or hear when the court is not in session is not evidence, even if it is said or done by a party or by a lawyer. Or by a witness, for that matter. You are to decide the case solely on the evidence that is received here in the courtroom during the trial.

Evidence may be direct or circumstantial. Direct evidence is direct proof of a fact such as testimony by a witness about what that witness personally saw or heard or did. Circumstantial evidence is proof of one or more facts from which you can find another fact.

You should consider both kinds of evidence. The law makes no distinction between the weight to be given to either direct or circumstantial evidence. It is for you to decide how

much weight to give to any evidence.

There are rules of evidence that control what can be received into evidence during the trial. When a lawyer asks a question or offers an exhibit and the lawyer on the other side thinks that it is not permitted by the rules of evidence, that lawyer may object.

If I overrule the objection, the question may be answered or the exhibit may be received in evidence. If I sustain the objection, the question cannot be answered and the exhibit cannot be received. Whenever I sustain an objection to a question, you must ignore the question and must not guess what the answer might have been.

Sometimes I might order that evidence be stricken from the record and that you disregard or ignore that evidence. As I mentioned, that means that when you are deciding the case, you must not consider evidence that was stricken.

In deciding the facts in the case, you may have to decide which testimony to believe and which testimony not to believe. You may believe everything a witness says or part of it or none of it.

In considering the testimony of any witness, you may take into account the opportunity and ability of the witness to see or hear or know the things testified to; the witness's memory; the witness's manner while testifying; the witness's interest in the outcome of the case, if any; the witness's bias

or prejudice, if any; whether other evidence contradicted the witness's testimony; the reasonableness of the witness's testimony in light of all the evidence; and any other factors that bear on believability.

Sometimes a witness may say something that is not consistent with something else he or she said. Sometimes different witnesses will give different versions of what happened. People often forget things or make mistakes in what they remember. Also, two people may see the same event but remember it differently. You may consider these differences, but do not decide the testimony is untrue just because it differs from other testimony.

However, if you decide that a witness has deliberately testified untruthfully about something important, you may choose not to believe anything that witness said. On the other hand, if you think the witness testified untruthfully about some things but told the truth about others, you may accept the part you think is true and ignore the rest.

The weight of the evidence as to a fact does not depend on the number of witnesses who testify about it. What is important is how believable the witnesses are and how much weight you think their testimony deserves.

I will now say a few words about your conduct as jurors.

First, please keep an open mind throughout the trial,

and do not decide what the verdict should be until you and your fellow jurors have completed your deliberations at the end of the case.

Second, because you must be the -- because you must decide this case based only on the evidence received in the case and on my instructions as to the law that applies, you must not be exposed to any other information about the case or to the issues it involves during the course of your jury duty.

Thus, until the end of the case or until I tell you otherwise, do not communicate with anyone in any way and do not let anyone else communicate with you in any way about the merits of the case or anything to do with it.

This includes discussing the case in person, in writing, by phone or electronic means, by email, text messaging, or any internet chat room, blog, website, or application, including but not limited to Facebook, YouTube, Twitter, Instagram, LinkedIn, Snapchat, or any other form of social media. I didn't have to give that instruction five years ago, but we do now. The point is, you don't communicate with anybody in any form.

This applies to communicating with your fellow jurors until I give the case to you for deliberation, and it applies to communicating with everyone else, including your family members, your employer, the media or press, and the people involved in the trial, although you obviously can tell your

family and your employer that you have been chosen to serve on this jury. But if you are asked or approached in any way about your jury service or anything about this case, you must respond that you have been ordered not to discuss the matter and to report any contact to the Court.

Because you will receive all the evidence and legal instruction you may properly consider to return a verdict, do not read, watch, or listen to any news or media accounts or commentary about this case or anything to do with it, although I have no information that there will be news reports about this case.

Do not do any research such as consulting dictionaries, searching the internet, or using other reference materials, and do not make any investigation or in any other way try to learn about the case on your own. Do not visit or view any place discussed in this case, and do not use internet programs or other devices to search for or view any place discussed during the trial.

Also, do not do any research about the law or the people involved in the case, including the parties, the witnesses, or the lawyers, until after you have been excused as jurors. If you happen to read or hear anything touching on this case in the media or in any other form, turn away and report it to me as soon as possible.

These rules that I have just described protect each

party's right to have this case decided only on the evidence that has been presented here in court. Witnesses in court take an oath to tell the truth, and the accuracy of their testimony is tested through the trial process. If you do any research or investigation outside of the courtroom on your own or gain any other information through improper communications, then your verdict may be influenced by inaccurate, incomplete, or misleading information that has not been tested by the trial process, and it could be influenced by information that these parties never had an opportunity to address.

Each of the parties is entitled to a fair trial by an impartial jury. And if you decide the case based on information not presented in court, you will have denied the parties a fair trial. Please remember that you have taken an oath to follow these rules, and it is very important that you follow them.

A juror who violates these restrictions jeopardizes the fairness of these proceedings, and a mistrial could result that would require the entire trial process to start over again. Again, if any of you is exposed to any outside information, please notify me immediately.

I urge you to pay close attention to the trial testimony as it is given. During the deliberations at the end of the case, you will not have a transcript of the trial proceedings. Even though we have court reporters here taking

down everything that is said, when they get to the end of a trial, they go back and proofread those transcripts and check them against the record and the exhibits to make sure they're completely accurate, and that takes days to do. That won't be finished by the time that you are deliberating, so there will be no transcript, and as a result, it will be important for you to pay close attention as the testimony is given.

If you wish, you may take notes to help you remember the evidence. If you do take notes, please keep them to yourself until you go to the jury room to decide the case. Do not let note-taking distract you. When you leave the courtroom during a break or at the end of the day, you can simply leave your notes on your chair. Nobody will read your notes, and they will be here for you when you return to court.

Whether or not you take notes, you should rely on your own memory of the evidence. Notes are only to assist your memory. You should not be overly influenced by your notes or the notes of other jurors.

From time to time during the trial, it may become necessary for me to talk with the lawyers outside of your hearing, either by having a conference here at the side of the bench, as we've done a couple of times this morning, or perhaps even calling a recess for a few minutes.

Please understand that while that happens, we are working. The purpose of this conference -- or these

conferences will not be to keep relevant information from you, but to decide how certain evidence is to be treated under the rules of evidence and to avoid confusion and error.

We will do what we can to keep the number and length of these conferences to a minimum. I may not always grant a lawyer's request for a conference. Please do not consider my granting or denying a request for a conference as any indication of my opinion of the case or of what your verdict should be.

Trials proceed in the following way:

First, each side may make an opening statement. An opening statement is not evidence. It is simply an outline to help you understand what that party expects the evidence will show. A party is not required to make an opening statement.

The plaintiffs will then present evidence, and counsel for the defendants may cross-examine. Then the defendants may present evidence, and counsel for the plaintiffs may cross-examine.

After the evidence has been presented, I will instruct you on the law that applies to the case, and the attorneys will make closing arguments. After that, you will go to the jury room to deliberate on your verdict.

Counsel, do you have any corrections or additions to the instructions?

MS. REED ZAIC: No, Your Honor.

MR. ROGERS: No, Your Honor.

THE COURT: All right. Folks, I don't know if you noticed it, but there's been a little static sound in the speakers.

You're losing that?

JURY MEMBER: I'm beeping, and when it starts beeping, I lose what you're saying.

THE COURT: Let's get you another one.

JURY MEMBER: Thank you.

THE COURT: Beeping means your battery is wearing out, so by all means, raise your hand when that happens.

You might have heard a little static on the speaker. That means somebody in the courtroom has their cell phone on. It doesn't work just to mute it. You either need to turn it off or put it on airplane mode, so everybody please check your cell phone now and make sure it's either turned off or on airplane mode.

All right. As I mentioned, ladies and gentlemen, there are some facts to which the parties have agreed, and you should treat those facts as having been proved for purposes of the trial. I'm going to read you some introductory facts that the parties have agreed to, and so these are established as accurate for purposes of the trial.

The defendant in this case -- the defendants in this case are C.R. Bard Inc. and Bard Peripheral Vascular Inc.,

sometimes referred to as BPV. BPV is a wholly owned subsidiary of C.R. Bard Inc., which is the parent company. As I mentioned, throughout this case and in the final jury instructions, we will simply refer to C.R. Bard and BPV collectively as "Bard" or as "defendants."

The product that is the subject of this lawsuit is a retrievable Bard IVC filter. And as mentioned, IVC stands for inferior vena cava, the large vein that returns blood to the heart. The Bard filter that is at issue in this case was manufactured, marketed, designed, and sold by Bard.

The plaintiffs and the defendants disagree on the specific identity of the Bard filter. Plaintiffs contend that the filter implanted in Mrs. Hyde was known as a G2X filter. Defendants contend that the filter was an Eclipse filter. Both the G2X and the Eclipse are Bard IVC filters; they're just different generations of the IVC filter. But there's a disagreement on whether it was a G2X or an Eclipse.

The filter is a conical device, conical in shape, that consists of a main shaft to which 12 struts are attached. And the struts are referred to either as arms or legs. The filter -- and you'll see examples of filters during the trial. The filter is constructed of a nickel titanium alloy called Nitinol.

The filter is a medical device and is implanted in the inferior vena cava, the largest vein in the human body. The

United States Food and Drug Administration, that will be referred to sometimes as the FDA, cleared the filter for commercial availability through what is known as the 510(k) process outlined in the Food, Drug, and Cosmetic Act.

The G2X filter was cleared for commercial availability in the United States for use in patients as a permanent filter with an option of retrieving the filter on October 31st, 2008.

The Eclipse filter was cleared for commercial availability in the United States for use in patients as a permanent filter with an option of retrieval on November 23rd, 2009.

The plaintiff, Lisa Hyde, was under the care of Dr. Shah, S-H-A-H. I can't pronounce his first name well. It's Vinodkumar. Dr. Vinodkumar, is my pronunciation, Shah. Dr. Shah referred Mrs. Hyde to Dr. David Henry, an interventional radiologist, to consult with Mrs. Hyde regarding possible use of an IVC filter.

On February 25th of 2011, Dr. David Henry implanted -- let me start that over.

On February 25th, 2011, Dr. David Henry implanted the filter in Mrs. Hyde's inferior vena cava. On May 6th, 2014, Mrs. Hyde underwent a CT scan, revealing that her IVC filter had fractured, with a fractured strut having migrated to the right ventricle of her heart.

On August 26th of 2014, Dr. William Kuo, which is

spelled K-U-O, removed the filter and the fractured strut.

All right. With those facts having been described, we will proceed now with the opening statement.

Ms. Reed Zaic?

MS. REED ZAIC: Just wanted to test that up on this monitor.

Good afternoon. I believe I introduced myself, and my colleague introduced myself earlier today during the jury selection process, and now you are the jurors that are now impaneled.

And beyond the -- or outside of the jury selection process, as the lawyers and representatives of Lisa Hyde and Mark Hyde, we don't get an opportunity to communicate directly with the jury. We get to do it now during opening and one more time before the end of the trial, so I wanted to take the opportunity to thank you for your service. Jury service is extremely important.

The judge has given an introduction to this case with some agreed-upon facts and some rules that have been stated to you to follow, not necessarily of your own choosing but --

Are you having an issue?

JURY MEMBER: Sorry.

MS. REED ZAIC: I think she's having an issue with her hearing, the device.

If that happens again, I'm sure one of us in the

course of who's standing here can get the Court's attention.

Is that working?

JURY MEMBER: Yes.

MS. REED ZAIC: Okay.

The judge has given you an introduction to the case, and as the attorney representing the plaintiffs, we get to go first. And that's good, but in a complex case, there are some issues, as the judge discussed, with acronyms and some phrases, and taking notes may be an issue. So if I'm repetitive, forgive me, but in describing the evidence that will come into this case, this being a complex case and being the first one to describe some of this evidence, I want to be very, very clear about it, about this device and about the anatomy.

But stepping backwards, you will be receiving evidence in this trial in many different forms. It will come in test -- the form of testimony, live witnesses, videotaped witnesses, documents. And some of the documents that you'll be looking at are actually Bard's internal documents within the company during the relevant time period.

As the plaintiffs, we believe that the evidence that will be presented to you will support the claims in this case. Those claims include that Mrs. Hyde received a Bard IVC filter. The judge has explained in these stipulated facts that there is an issue and a dispute over which filter she received, but there's no dispute that it was a Bard filter.

Second, we believe the evidence will support the fact that this filter in its design was defective. It did not meet the specifications and the risk analysis internally that Bard developed for these filters, and that there was not long-term testing on these filters to predict what might happen to Mrs. Hyde when she received the filter. That includes the fact that the filter, when it was inserted into her, broke apart and one of the pieces traveled to her right ventricle, which was not part of the design of this filter.

Now, again, I get to go first, but I want to go back over something that the judge described. The inferior vena cava, the IVC, the largest vein in the body. The idea behind the device, an IVC filter device, is that we have a large vein and a large artery, to put it in very simple terms.

If you can see on your screens, the IVC, the inferior vena cava, is the largest vein in the body, represented by the blue column. This is the vein that returns blood from your lower extremities back up to your heart to be oxygenated again, to travel back to your body and keep your tissues healthy.

So the aorta, the largest artery in the body, sends the blood away from the heart to oxygenate, and once the oxygen is depleted, that oxygen comes back up through the IVC, the inferior vena cava, as the highway back to the heart and through to the lungs.

The concept of the filter, the evidence will show, is

that once it is placed in a patient who is at risk for DVT, deep vein thrombosis, which are clots that form in the lower extremities -- and if they form, they might travel up through this vein, the largest vein in the body, to the heart and to the lungs, and that can be very dangerous.

So the concept of an IVC filter is a medical device inserted in patients at a higher risk for DVTs to potentially catch a blood clot if it forms, so that like the blood traveling back to the heart and the lungs, it does not go there.

So I have an animation to show the insertion of an IVC filter and to give you a better example, or in the context of the evidence coming into this case, the organs that surround the IVC.

This is not Mrs. Hyde. This does not depict her specifically, but again, the general depiction of the anatomy of the body. The lungs to the left and right. The heart in the center.

As we step behind them, you'll see a moving version of the cartoon that I just displayed, with the inferior vena cava on the left. And the depiction generally of a filter in the vein.

And this area, you'll hear from expert witnesses in the case, is an area that is very active with blood flow. And as you can see, it also moves. It's a very, very dynamic area,

with the filter affixing with the intention of catching any potential blood clots that form in the legs, if they form and if they travel.

So this is the general anatomy. You can see the organs that are close by the IVC, close by that filter, inside an IVC generally. And with that short anatomy lesson, let's step back to the actual filter and the filter history.

Bard has a long filter history, starting in the 1990s with a permanent filter. In the 1990s, stepping back in time, if you recall, definitely a different era. In that time period in the medical device world, IVC filters were permanent. They were not designed to be placed and retrieved.

And testimony in this case from expert witnesses -- there will be experts on both sides. It will not surprise you they won't always agree. But testimony will come into this case through experts stating that once this device is placed and can't come out, it's there forever. And that leads to a decision in a patient's care, to make a decision to put a device in a patient permanently. And that was the situation in the 1990s.

Bard -- I'll add to some more acronyms, as you can see up on the screen. Actually, it's not on this slide, but I'll add to your list of acronyms. Bard had an SNF filter. It was called the Simon Nitinol filter. Mr. Simon was a doctor, he was a physician, who invented this version of a permanent

filter that Bard acquired from a company called NMT. They acquired the technology and had a permanent filter. I have under this slide that it's 1995. They actually originally had this filter in 1990.

But as these filters come on the market, the regulatory pathway that they go through builds upon the previous design or builds upon other filters, which is how Bard got their filters cleared.

So in the 1990s, the permanent filter that Bard had was the SNF. To give you a general overview of the continuum, as Bard went forward, again, a segue of what you're going to see a preview in a bit, their first retrievable filter was called the Recovery filter.

So the Simon Nitinol filter was first. It was permanent. They developed a retrievable filter, permanent filter that could be retrieved.

Then they developed the G2, developed the G2X, which as you heard is one of the filters -- is the filter in dispute in this case. But there is a dispute between which filter Mrs. Hyde had. The other one -- I've outlined them in red -- is the Eclipse. And the one that came on the market, developed and manufactured and marketed by Bard, was the Meridian filter.

So now heading backwards, starting with the SNF, like I said, it was -- acquired the technology from the NMT company. I mention that because you may see it on documents in evidence

coming into the case. Not to be confused, it is a Bard filter. It was a permanent filter that Bard's own employees expressed, including their medical director, had an impressive safety record.

But as I mentioned, it was the 1990s and towards the end of the 1990s, and my mention of testimony that would come into evidence regarding the fact that these were permanent filters, and decisions needed to be made about placing something permanently in a patient forever with no design to get it out at the time it was manufactured.

The state of the medicine in the end of the 1990s and into the early 2000s is that there was a desire in the medical community, specifically the interventional radiology community, where you have a radiologist that reads a different array of films, you have interventionalists that may go in and do procedures on patients while viewing them at the same time.

And amongst the interventional radiology community that would place a lot of these permanent filters, there was a desire to have a device that you wouldn't have to leave in permanently. It would go in permanently, and you could have the option of taking it out.

There were filters that were available for very short-term retrievals, short term as in about two weeks, but again, that desire of being able to put in a filter to protect -- with the intention of protecting a patient from

potential blood clots going to their heart and lungs and leaving it for a period of time and taking it out was very attractive and very desirable to the interventional radiology community.

And towards the end of the 2000s, I anticipate the defendants will bring evidence in about a report from the Surgeon General called "Call to Action." Blood clots can be a serious injury. And in 2008, the Department of Human and Health Services held a workshop. It resulted in a paper being published by the Surgeon General called "Call to Action" about how dangerous blood clots could be. So this is an issue that was known, and interventional radiologists in the early years of the 2000s wanted different options.

Seeing as there was no filter on the market in the late '90s and early 2000s that could satisfy this desire of wanting a retrievable filter, there was quite an opportunity in the market. And the first company that could develop one of these permanent filters that could also be retrieved would lead the market. They would have the lead market share.

So Bard having acquired the technology for a permanent filter called the Simon Nitinol, when they acquired that technology, also in development was a retrievable filter, a permanent filter based on the original design of the Simon Nitinol filter that could be placed and retrieved. These devices at this time, before clearance to the market, had not

been tested in humans.

So let me describe some of the testing that went on. First of all, the first step was to test it on the bench. And the bench in a lab is simply a piece of furniture. I've got a depiction of a very clean one there. A bench will be in a laboratory with equipment and testing equipment on top or on the side or around, and this is where bench scientists perform tests that are -- don't occur in the human body.

There was also animal testing going on in sheep, developing this first retrievable filter that Bard wanted to send to market first. One of the tests I'll describe -- actually, several tests that went on looked for filter failures that were happening very rarely in the permanent filters before retrievables were developed. That included the tilting of the filter.

The design was desirable if it would go in and stay in place. A medical device, when it goes in, needs to stay in place, especially in an environment, you'll hear from our experts, where it -- as I showed you in the little movie, that the blood flowing through there and the movement of the vein, stability was very important in the highway back to the heart.

So they would do benchtop testing for tilting to make sure that it would center. They would do benchtop testing to make sure it wouldn't perforate that vein. You saw the other organs that were surrounding the vein, that it wouldn't

penetrate. It wouldn't go to the aorta or the spine right behind it. They also did testing for fracture resistance.

They would do different tests and cyclical tests, you'll hear from one of our engineers. He may actually -- you may actually hear from him this afternoon if I can get through this fast enough, yet still understandably, that there was testing about fractures on these devices to make sure that they would stay intact. A fracture is what actually happened in Mrs. Hyde.

And they also tested for migration resistance. And if you look on the screen right now, the very first one I have is a very short description of a migration resistance test. For example, the tests that they used originally with their first retrievable involved PVC pipe to simulate the vein. They lined it with sausage casing. They deployed the Recovery filter to see if it would tear or other failure methods, but the one I'm describing is migration resistance, which was very important, because again, as you saw, the blood was flowing. You don't want it to move.

Pressure is the measurement for migration resistance. The goal is to make sure that this filter can resist the pressure coming from below it.

And you'll see in later slides, and you'll see in evidence throughout the trial, the measure for pressure is millimeters of mercury, which is a really easy way to describe

the method of a thermometer and how it measures temperature. There are ticks on the thermometer. The mercury goes up the higher the pressure of the heat. The symbol for millimeters of mercury is mmHg, millimeters of Hg, which are two Greek words for liquid silver, I believe.

So if you see those terms, that is a measurement of pressure. The higher the number, the better the filter can resist that migration pressure. And resist is what you want it to do.

So with their bench testing and testing for those different failure modes that they had seen rarely in the permanent filters, and with the migration resistance testing that they also did in animals, one thing they didn't have is any human testing.

And again, the goal was to make this a retrievable filter. So the initial clinical study done, and the only clinical study done on humans on retrievable filters up until the mid-2000s for Bard's filters, anyway, was done in Canada.

And why Canada? Dr. Murray Asch, the interventional radiologist that ran the lab and was the study director, will testify by videotape. It was because of the regulatory pathways. It was easier for them, "them" being Bard, to come to Canada to have the study done than to have it done in the States. It was easier to get permission to use an experimental device in Canada. So Bard took this study to Canada, and

Dr. Murray Asch ran it.

Now, studies always have to have an end point, and Bard wanted to know if this filter could be retrieved. The study did not test anything except the insertion and the removal. It did not study long-term safety. It did not study placement long term. It was a six-week test in 35 patients with the goal of determining if it could be removed successfully.

And these are some of the results. There were 22 procedural difficulties, there were five tilts, one perforation, one caudal migration. Caudal means down to the feet. There was one cephalad migration. Cephalad means up to the head. So sometimes the filter would go up, sometimes it would go down. There was one arm fracture, which is the failure mode that Mrs. Hyde suffered with the arm breaking on her later filter and going to her heart. And there was one fractured leg hook.

On the bench, the testimony will show, Bard was already witnessing that its first retrievable filter moved more. It did not stay as stable as the earlier permanent filters and when compared against its own permanent filter, the SNF.

But the study was successful according to Dr. Asch, and that is because it met its end point. Recall, the end point was to see if it could be retrieved, not long-term

safety, not the effects of what would happen in a human being if it stayed in long term.

So Bard packaged up its data, put together a submission, and sent it to the FDA.

Now, let's take another segue here. More testimony and evidence you will hear in this case about the FDA. There are two ways to get your medical device on the market in the United States.

The first one is PMA, premarket approval. None of the Bard devices went through this pathway. Premarket approval actually approves a medical device. You get a stamp of FDA approval. It is an independent safety review of that device. IVC filters generally do not go through that pathway. Per FDA regulations, Bard's filters did not go through that pathway.

The second method of getting a medical device to the market in the United States through the FDA is called 510(k), which is similar to a -- it's a code section of the law. Sort of like your 401(k) is a tax code, the 510(k) is a code in the FDA regulations explaining the rules and the regulations you have to follow and the submission required in order to get clearance. It is not safety review.

When you go through the 510(k) process with your medical device, your device at the end is not FDA approved. It is cleared. Now, those two words get twisted -- get interchanged quite a bit when people are discussing generally.

Lawyers do it. Judges do it. Witnesses do it. They interchange them when talking about the fact that it's been permitted to be sold in the United States.

But there is a very clear regulatory and legal distinction that our experts will discuss between these two. 510(k) gives you clearance for your device, not approval. It's an honor system. It is not an official approval nor a determination by the FDA that the product is safe and effective.

The 510(k) process does not approve or certify the design of the medical device. It clears it. And the basis for clearing it as opposed to the PMA process of review and providing independent safety review, the standard for the 510(k) process is a comparison.

If you take your medical device and you have what is called a predicate, a device that is already on the market, which also can be through the 510(k) process, as long as it is comparable and substantially equivalent with regard to safety and efficacy of a device already being sold, that is the standard. If you can show the FDA it doesn't raise any new safety concerns and it's comparable to another device that's already being sold, you can get your medical device cleared for sale.

The manufacturer has to certify to the FDA that its information it has submitted in the 510(k) application is true

and accurate. They have to provide this with their submission. The FDA is not responsible in the end for the safety of those devices. Our regulatory expert will explain that very clearly. The manufacturer, at the end of the day, is responsible for the safety of the product it manufactured, not the FDA.

Again, it's an honor system. The FDA does not independently test these medical devices. Every single one of the applications that will come into evidence, the FDA did not test it. The FDA did not go in and individually independently verify the test data that came in to the FDA. It relies on the manufacturers to be accurate.

And as I mentioned, after bench testing, animal testing, and a short-term clinical trial evaluating the ability to retrieve the device, Bard submitted a 510(k) application to the FDA for clearance. And when it received it, it was the first to market with the very first permanent IVC filter that could be retrieved. Again, through the less rigorous process of the FDA.

It was cleared as a permanent device in 2002 initially, and once Dr. Asch's data was submitted, it got the clearance in July 2003. I go back and point that out simply because the next slide, I want to point out that once it was on the market and being marketed as a retrievable filter, the initial first retrievable filter manufactured by Bard, designed, manufactured, and sold, started to experience adverse

events.

By December of that year, they were already discussing the design review. Within three months, there were questions about the testing. I mentioned the 50 -- the millimeters of mercury standard. The original specification was that the Recovery filter needed to resist 50 millimeters of mercury, and they were questioning that because of the adverse events that were being reported. There were migrations of this filter indicating the pressure test may not have been accurate, may not have been adequate.

Once it was cleared in July 2003 for retrievability, by October, November, and December, they were seeing migrations in both directions, towards the head and towards the feet in a caudal fashion, and fractures.

And by the first of the next year, they experienced their first catastrophic injury reported with their first retrievable filter, the Recovery. By April, they had experienced their second. It had been reported to them a second catastrophic injury of a filter migrating.

And I want you to look at that date, April 14th, 2004. Within 12 days, Bard was redesigning the filter while the first one was still on the market. They were coming up with their next-generation G2 filter. Stands for Generation 2. It was also called the modified Recovery.

I make these segues because as you see the evidence

come in, it might be called those things. The modified Recovery, the G2, the G1A. There's different references to it, but the point being is that based on the limited clinical data that they had, and once it was cleared to the market, the clinical data that was coming in was being experienced by patients who were receiving the filter.

They sat down and discussed a redesign while still selling the Recovery. And internally, they were conducting health hazard evaluations. So as written by their medical director at the time describing, in the first line, you'll see the catastrophic injuries.

They had also reported -- also received reports of 17 reports of limb fractures. It was breaking apart. A total of 20 arm fractures were reported in 14 cases. 20 arm fractures in 14 cases means more than one arm was breaking. And 11 of the 20 arms remained in the patients, with six patients, and detached arm migrations to the heart or lungs.

The MAUDE database contained 25 reports of filter fracture. And Dr. Ciavarella, their medical director, goes through and looks at the events as they're being reported. The MAUDE database, I will do a segue and explain later, it's the FDA database of reports that come in to the FDA of adverse events.

But the date of this is July 9th. It was approximately one year. They're still receiving reports of the

first retrievable device the first year that it's on the market.

Another segue. You will not hear evidence from the plaintiffs that there is any medical device on the market that is 100 percent safe. The testimony and evidence will actually show that all medical devices carry risks.

But when manufacturers design a device, they need to make it safe for patients, and they need to guard against defective conditions. And the evidence that you will see coming in with regard to their testing shows that their testing in humans, especially, was not reasonable or adequate.

And as the reports continued to come in with the first retrievable device, their marketing director actually stated in an email, "We knew very little about the long-term clinical performance of this device when we launched it."

And as I mentioned, they began their redesign, Generation 2. Using the Recovery filter this time and not the Simon Nitinol as the comparator for their 510(k) application to the FDA to get it cleared, they redesigned the Recovery, made the G2.

If you look at the pictures, they took the arms and made them longer. And the evidence will show the decision to do that was to try and prevent these migrations that were happening with the original device.

It went on the market in August 2005. And when they

began to market it, it was only as a permanent filter. Because similar to the first time when they submitted the 510(k) application for the Recovery, their first retrievable, they didn't have any data to show that they could retrieve it.

So when the G2 was officially cleared for market, the second generation, they marketed it as taking strength and stability to a new level based on their redesign, increased migration resistance, improved centering, and enhanced fracture resistance. They sold it as a permanent filter because they did not have the data yet.

But data is coming in. Reports of adverse events from the field are coming in again with the second-generation G2 filter. And the medical director, once again, "I'd like to look more generally at the G2 complaints. I've seen problems with caudal migration, tilting, perforation, mis-deployment, and maybe one or two others. The G2 is a permanent filter. We also have one, the SNF, that has virtually no complaints associated with it. Why shouldn't doctors be using that one rather than the G2?"

The evidence, through Dr. Ciavarella's testimony, will show that there was a safer alternative, and it was their filter.

But there were competitors coming into the market at this point. Bard was no longer the sole provider of the first retrievable filter that could be left in permanently or taken

out as they advertised, and so they began to set up another clinical trial, enrolling patients -- similar to the Asch study but a little bit bigger -- in order to collect that one data point of inserting it and being able to retrieve it so that they could then market it as retrievable.

On the previous slide, I showed you Dr. Ciavarella commenting on the safety aspects of the SNF compared to the G2. That was in December of 2008 -- I'm sorry, 2005.

And in that same month, they began enrolling patients in a small clinical trial to get the retrievability indication. And this is what it looked like. 100 patients. Six months. Not permanent. Not long term. End point, retrievability.

When the study was completed, 91 patients completed the study, 52 filters were able to be retrieved, and there was no follow-up with these patients for six months.

Important to note is that clinical trials have a medical monitor, and someone who monitors a clinical trial looks at the adverse events as they're coming in. And the medical monitor in this trial, called the EVEREST trial, I'll point out, his name was Dr. Krish Kandarpa. As the medical monitor, he was assigned with the duties to look at adverse events and also to provide input to the sponsor, who was Bard.

At the initial meeting, he had some questions. One of the questions was: What were the problems you faced with the old device?

Bard's answer was: Legs breaking off or getting caught.

He also asked: At what point must the filter be considered permanent?

And Bard's response was: Six months.

So once that G2 filter went in, they relayed to the medical monitor in the clinical study for retrievability, at what point is it considered permanent and no longer retrievable? The answer was six months.

During the course of the clinical trial, Dr. Kandarpa, as the medical monitor, became concerned about the number of adverse events that were coming in through the clinical trial. Over 50 percent of the patients had had an adverse event or serious adverse events.

The evidence will show Dr. Kandarpa, who will appear by video testimony, suggested that it could have used a redesign at that point. Again, looking back, thinking of my slide about the continuum of these devices, this is the history of Bard's retrievable devices and the design elements that went into it.

Testimony and evidence you will see and hear in this case will talk about the results of the EVEREST trial. And what's important here to see is that there were overlaps between the adverse events coming in. It wasn't just singular adverse events. Sometimes they were happening all at the same

time.

So where there were 12 penetrations of the filter penetrating the vein reported in a 91-person study, they were coupled with other adverse events. And testimony and evidence will show that is when the failures happened. When these events come together, not just a singular fracture, but a migration, a tilt, and a fracture, that is when the filter becomes more dangerous.

In the EVEREST clinical study, Bard took a look at the data, and they also took a look at the MAUDE database, which I'm going to explain in a minute, the FDA database that collects adverse events. And one of the internal discussions they had -- this is directly from evidence that will come in on a PowerPoint slide reporting back about the EVEREST clinical study.

"Caudal migration, tilt, perforation, and fractures are the most commonly occurring complications associated with the filter." This is the G2. "Eliminating these failure modes would reduce number of filter complaints from 152 to 34." That's by 78 percent.

This internal discussion was not submitted in their 510(k) application to the FDA when they submitted the EVEREST data to get the permission to sell the device as a retrievable device.

And when I say they took a look at the data and they

took a look at the MAUDE database, evidence will come into the case about the MAUDE database. I anticipate that the defendants' evidence will suggest that the MAUDE database is not to be used to calculate rates.

This is actually a screenshot from the FDA database, and it's not complete. I've taken the headers to explain what it is. MAUDE stands for Manufacturer And User Facility Device Experience.

And there is a quote that says, "The incidence or prevalence of an event cannot be determined from this reporting system alone due to potential underreporting of events and lack of information about frequency of device use."

In the United States, the reporting system to the FDA is voluntary, whereas a manufacturer and some people involved in the manufacture and distribution of medical devices are required by regulation to report adverse events that come in to them. For example, if an adverse event is reported to Bard, they are required under the regulations to report it to FDA. And that information goes into the MAUDE database, which is publicly available.

But they're not the only reporters. Doctors report. Patients report. Individual family members report adverse events. But they're not required to. And that is the point. One of the weaknesses of a public database like MAUDE is not all events get reported.

And Dr. Ciavarella, Bard's medical director during the relevant time period, actually testified that the underreporting involves 1 to 5 percent, meaning only about 1 to 5 percent -- as he says, there's a consensus. About only 1 to 5 percent of adverse events are reported to the FDA.

And the last quote I have down there is that "MDR data," which is medical device reporting -- more acronyms. "MDR reporting" -- I'm sorry, "MDR data alone cannot be used to establish rates of events, evaluate a change in event rates over time, or compare event rates between devices."

But the evidence will show that's exactly what Bard did. That is the information that they began to use about their competitors.

Fractions. If you use them or you remember them, you'll remember there's a numerator and a denominator. And one of the issues with the FDA indicating you shouldn't use this information as a rate is because it's only the numerator. You only have a number of events. The denominator would be the units, the devices. You have to have a division. That's what creates a rate.

But Bard knows its rates. It knows its adverse events because they're reported to them and they report them to the FDA, and they know how many units they have sold. But the evidence and testimony will show that they can also get these resources from their competitors.

They can see how the competitive device is performing by looking at the number of adverse events. Although underreported, it's fewer than actual, they can look at how many events have happened with a competitor, such as a fracture of a competitor's device. And they have resources that they can gather estimates of the number of devices sold and create a rate, and Bard has used this information internally in the past.

Again, EVEREST end point was retrievability. They were able to retrieve the device in a short-term study with a few number of patients. They were able to package that device application for 510(k) clearance and submit it to the FDA.

And the predicate that they used this time, remember, was this Simon Nitinol, then the first retrievable was the Recovery based on the Simon Nitinol, and then the G2 based on the Recovery. Now the G2 has based itself on itself. The original application to get permanent clearance, and now they have a study with data showing that it can be retrieved.

So between August of 2005 and January of 2008, Bard did not have a device on the market that was retrievable. But the 510(k) application went in in light of the -- despite the data of EVEREST of the failures.

The FDA does not conduct their own tests, recall. This is a less rigorous pathway. The FDA does not independently dig underneath and interview and verify the data.

And Bard did not provide that internal discussion about if we reduce the complaints by this amount, we could eliminate up to 78 percent.

And again, between 2005 and 2008, they had no retrievable filter. And the evidence will show they were trying to keep their market share, so they continued to issue and get clearance for additional devices. Again, it was a long continuum I started with.

So once the G2 device, the G2 filter itself was cleared for permanent placement, three years later it was cleared for retrievable placement. And in the absence of a newer filter coming out, they also changed the device systems. Same filter, changing the device, adding a hook at the top. A benefit of retrievability, is the way that they market it.

And by October of 2008, the G2 filter that had gone through the EVEREST trial, reports coming in, being compared to the original permanent device as not as safe, it is now the G2X with the hook on the top, the same filter. And this is the filter that Lisa Hyde received.

Again, there is a dispute over which one she received, in full candor, but this is the one that we feel the evidence will support that she received. It was cleared in 2008. She received her filter in February of 2011.

And part of the specifications -- we've been talking about design. Part of the design specifications originally for

the G2 filter, you'll see on the screen. Clinical terms. The intended use. Permanent or temporary. And user needs include permanent or temporary.

There's also a dispute, you'll see in the evidence as it comes in, as to whether Lisa Hyde needed a permanent or a temporary filter. But the evidence will show that the design specification for the G2 filter was for permanent or temporary. That is the way it was designed.

Those are the specifications, including the fact that the medical monitor asked the questions: At what point does the G2 filter become permanent? And Bard's answer was: At six months. So despite permanent or temporary, the specification is that it's supposed to be both.

And again, competitors had entered the market by 2008, so this was also about the same time, the evidence will show, that the Surgeon General's report was released about the problems and the concern about blood clots.

As you can see in the top line of this SWOT, which stands for Strengths, Weaknesses, Opportunities, and Threats -- it is a marketing term. And the objective was to increase revenue and capture more market share.

This is evidence that will come in as a PowerPoint presentation that was presented discussing gathering more market share for this particular area of devices. And the issues that came up were a lack of thorough understanding of

the dynamics of caval anatomy. Remember, going back to the initial retrievable filter, there was commentary that it was released without long-term clinical data and how it might perform.

They also mentioned: We have historical reactive evolution design mind-set. Product complications forcing focus on reactive designing. And a limited understanding of user needs.

So by May of 2008, they're discussing the market and how they would like to gather more of a market share.

To quickly recap, they started with the SNF, the permanent filter. Their first retrievable was the Recovery, which was based and predicated on the Simon Nitinol filter. In August of 2005, the G2 filter was a redesign of the Recovery based on the adverse events that were coming in. There were no human clinical trials other than the initial 35-patient study with Dr. Asch in Canada.

After the EVEREST trial that I just described with Dr. Kandarpa as the medical monitor, the data was packaged and they received a retrievable indication and could market it that way.

By June of 2008, the G2 filter was out. If you look at these dates, in July of 2003 with their first retrievable, the Recovery, and June of 2008 -- excuse me, I believe that date is wrong. It is October 31st, 2008, the G2X was cleared

for market. I apologize. Just noticed that.

But the point being is that in five years, they've had four filters in a competitive market. And they designed another one. The Eclipse filter, which was, the testimony will show from their lead engineer, a G2 filter that was electropolished. Electropolishing was a buffing and polishing of the surface in an attempt to reduce fractures.

And despite the dispute of whether Lisa Hyde received a G2X filter or an Eclipse filter, it fractured regardless of the specifications and increasing fracture resistance in the Eclipse filter.

The next generation was the Meridian filter. The reports that were coming in over the years associated with Bard's retrievable filters is they were moving and they were not stable.

By 2010, they had developed the Meridian filter that was essentially the G2 filter with an addition of what they called caudal anchors. They looked like little anchors on the arms of the filter to stabilize it and keep it in place, and the testimony will show that was an effort to make it safer.

But the issue I want to point out here is that Lisa Hyde received an Eclipse filter in February of 2011. Those were the filters that were on the shelves at her hospital, the evidence will show. And during that time period, they had already submitted, two generations later, a filter for

clearance to the FDA. There is no evidence that sales representatives were asked to go and get old filters, whether it was the G2X or the Eclipse.

By 2010, they had a filter that they marketed, were trying to market, as even more stable. They had the filter itself. It wasn't a concept. It wasn't a prototype. It was one that they thought was safer.

So at this point in the continuum, you have the medical director saying originally with the G2 -- questioning why doctors would be using it instead of the SNF. Then you have the Meridian that was already submitted to the FDA when Lisa Hyde got her filter.

This is one of Bard's own documents showing these filters and how similar they were. The original G2. The G2 Express, where they've indicated the only change is the hook. It's the same filter. The Eclipse filter was electropolished to reduce fractures, but it was still in the G2 family of filters. And the Meridian I just described, that was submitted to the FDA prior to her getting her G2 filter, added caudal anchors to stabilize the device.

And regardless of whether Lisa Hyde needed a temporary or permanent filter and regardless of whether it was a G2X or an Eclipse, the safety characteristics based on Bard's own risk analysis, you can see on the screen for the G2X, the Eclipse, and the Meridian, all had the same language. The

characteristics related to the safety of the device. What determines the lifetime of the medical device? The comment is: The intended implant duration is for the life of the patient.

Lisa Hyde's filter, whether a G2X or an Eclipse, did not live up to this internal risk analysis. It did not survive the life of her. It malfunctioned and broke, in opposite to the specification and the analysis.

As I mentioned, SNF was indicated by the medical director as a safer device. The Meridian was already submitted as a safer device to the FDA before she received her filter, Lisa Hyde.

And this is the specification for the Meridian. Again, a product performance specification for a device that in 2010, before she received her filter, they had already run these tests on and developed these specifications.

I'd like to point out -- if I knew how to turn on the red dot -- the column that starts with the word "OptEase." It is in yellow.

The OptEase filter is a competitor. And when they were designing these specifications and testing this device, this later device with caudal anchors to make it more stable, they had done an analysis with the OptEase, their competitor. It has an acceptable clinical history of caudal migration resistance as well as a lower complaint rate for caudal migration then G2, G2X, and Eclipse.

And the information that they pulled in order to develop that standard, that specification for their next product, was the MAUDE database. This is one of the failure modes that the G2X filter and the Eclipse filter suffered from, caudal migration.

So this is three, by my count. The testimony and evidence will show three different safer alternative designs to the one that Lisa Hyde received. And the next slide -- I should have gone to it first. I'd blown up that small language I was trying to send you to. The OptEase has an acceptable clinical history, has a lower complaint rate for caudal migration than two of the filters in dispute in this case.

So looking back, even at this point, even with the Meridian, there was no long-term clinical testing of these retrievable devices. There were a total of two clinical trials that Bard sponsored, put together, designed, and run and collected data from. They were small patient pools, one 35 patients, one under 100 patients. One was for only six weeks looking at retrievability, and one was only for six months. There was no human clinical trial data on the long-term use of leaving this in permanently.

I anticipate during the course of this trial the evidence that the defendants will bring in in defense of this is that the failure rates complied with industry standards. And one of the documents they will introduce is called the SRI

guidelines.

But evidence and testimony and expert witness testimony, including some of Bard's own witnesses, will indicate that these guidelines were never intended to predict risk. They were not intended to be a tool to reduce risk, and they were not intended to guide manufacturers as to the safety of their devices.

And with regard to efficacy, Bard's own medical -- excuse me, marketing director, not medical director -- marketing director, Janet Hudnall, who you will hear from, admitted that there is no way to know if a filter has ever stopped a clot. Developing a DVT, it converting to a clot that travels, there is no study to show exactly how many times a filter actually stops a clot.

And in 2008, when the Surgeon General's report came out concerned about blood clots, there's been information that's come out since, including a report -- a retrospective analysis. In other words, not a clinical trial that Bard put together looking forward, but going back into patient databases and pulling information on people who have had IVC filters.

And you will hear his testimony that in a retrospective evaluation of an analysis of looking at patient data, 30 million people: We do not know based on this study of 30 million people whether or not vena cava filters were effective in decreasing the rate of fatal PE, which is

important. That was after the Surgeon General's report.

There will also be medical literature that you'll hear about discussed amongst the experts that came after that 2008 report, including a paper by a gentleman with the last name Angel, who did a study of the G2 filter in particular and looking at the available medical reports.

84 percent of all reports of IV filter fracture to the United States FDA were that of the Bard filter. And they're responsible for 59 percent of all reports of adverse events to FDA concerning IVC filters. Again, the science developing after the Surgeon General's report.

In addition to the medical director touting the Simon Nitinol filter as a safer alternative to the G2 and the early development of the IVC design history for Bard, the sales force was also saying: May I suggest the filter on the market that has been on the market for the longest time in its current form, the Simon Nitinol. You want a filter that will give you the greatest chance of reducing your complications. The Simon Nitinol is that filter.

I have a spreadsheet from MAUDE that shows this.

I want to change gears a little bit about the dispute between what filter Lisa Hyde received.

You'll hear from marketing individuals in this case that will testify live and by videotape. And one of the communications that went out to the sales staff in April of

2010 -- this is almost a year before Lisa received her G2X filter -- was an indication to the sales team that: We have officially stopped selling G2X in the United States and have transitioned over to the Eclipse.

Again, remember, the continuum was the G2, the G2X, then the Eclipse, then the Meridian.

So after they had developed and gotten clearance for the Eclipse filter, this memo went out saying: We're not selling the G2X anymore. We're transitioning to the Eclipse.

But as I mentioned, there is no evidence that Bard sent an edict or a directive for sales individuals to go out to hospitals to make sure that hospitals were changing out their inventory. If they purchased them beforehand and the inventory was still on the shelves, there was no directive from Bard to take those filters off the shelf and arrange some replacement or buyout for them to have the newer filters. That was in 2010.

In February of 2011, just days before Lisa got her filter in February, on February 25th, there was an email exchange between the sales representative in the region of the hospital in Wisconsin where Lisa Hyde received her filter. The response was they still had G2 in stock. Days before she received her filter.

And after she received her filter, in April, if you read from the bottom up as emails go, Matt, who was the sales

representative, Matt Fermanich: I have two G2 filter systems that have expired, with the reference numbers. Would you please be able to replace these?

His response: Cynthia, I'm more than happy to help you out there. First, the G2 filter system is being phased out.

This is after she received her filter. Phased out. Not "We're not selling it," not "It no longer exists," not "You shouldn't have it on your shelves." It's being phased out. We have a new filter called the Eclipse, which is of the same design of the G2 but has a few new features included. First, the hook on the top, allowing for snare retrieval as well as the normal cone retrieval. Second, the filter itself has been electropolished, as I described, the G2, to lower fracture resistance.

As I pointed out earlier, regardless of whether it was a G2 or an Eclipse, the evidence will show that the design specification and the safety and risk analysis were the same in the sense that they should be temporary or permanent, regardless of which one she received.

Now, I really want to switch gears and talk about Lisa Hyde. I have it on the slide here generally for your dates -- because again, you're limited to taking notes -- that in February she was diagnosed with a pulmonary embolism.

Lisa Hyde, she will take the stand and she will

testify. She's a mother of three. She is extremely devoted to her children. She's been married to Mark, who was an air traffic controller at the time when they were living in Wisconsin. She has a protein C deficiency, and those sorts of hematology illnesses do make people prone to DVTs.

She had a DVT, and she went to the hospital. And it was recommended that she receive an IVC filter to protect her for the potential of a clot traveling to her lungs, and she had had a history of this happening before.

You'll hear from Lisa. She agreed to this procedure and to have the filter, believing and expecting that this would protect her and this would help her, a mother with three young children. It was important to her.

Between February and May -- let me back up and tell you a little bit more about Lisa and Mark. They lived in Wisconsin at the time that this happened. Mark was an air traffic controller. He was transferred to Las Vegas, Nevada, to McCarran International Airport, as an operations manager. So that may explain the background of why we were in Wisconsin and why they live in Las Vegas now.

They've since retired, and they spend a lot of their time doing volunteer work. And their youngest daughter was a later production, so she's still only in high school. So they are at home and active with their daughter.

Between 2011 and 2014, after she received her filter,

Lisa in 2012, 2013, started to experience various complaints of pain that she couldn't quite put her finger on. She went to a series of doctors' appointments and saw different doctors trying to diagnose this and didn't know what it was.

In May of 2014, the pain became bad enough that she thought she had a kidney stone and went to the doctor, and they gave her a CT scan. And it was found incidentally while checking her for a kidney stone that her filter had broken, and part of it had traveled to her heart. It was in her right ventricle.

In looking at that CT scan, you can see the placement of it, and it was also butted up against -- it had perforated and penetrated through the vein, and the legs had come in contact with her vertebral body.

Lisa will take the stand and she will describe what it was like to experience that, the cold fear. And the only thing good about that day is she finally had an answer to what had been causing her pain, what -- what was it. She had been through several doctors' appointments to figure it out and incidentally discovered that this happened.

When she describes finding out about that, she will relay her medical history to you and her doctors' visits and what she was told. Her doctor had not seen this before. She was referred to a cardiologist. The cardiologist had not seen this before. But he immediately told her -- and she'll explain

this to you in her testimony as part of the evidence that comes into trial. He explained to her: You need to not do anything that will raise your heart rate.

With a piece of metal in her heart, she will explain to you that during the course of her treatment with him, he relayed to her that: You're one beat away from this possibly going through your heart.

This was May. They had a trip planned to go to Wisconsin. They had moved to Las Vegas. They wanted to go back and see some family members. Lisa, when she takes the stand, you'll understand, who does not take anything lightly, in dealing with the cardiologist and not having immediate answers, went to find her own answers. She went on the internet, Googled it. She had not heard of this before, and the shock she will relay to you in looking for treatment and options and how did this happen.

She came across a doctor online who specialized in removing broken pieces of IVC filters. She went back to her cardiologist, who had done research since then, and Dr. Kuo, who was the doctor, I believe the judge mentioned his name, K-U-O, called her and said, "I believe I can get this filter out. I don't know if I can get the piece out of your heart. And consequently, if we can't get it out, it will be open heart surgery."

So in dealing with her cardiologist, dealing with this

doctor that she found who could treat her, who was in Stanford, California, he couldn't get her in until August. She was under the care of her cardiologist, who told her: Don't raise your heart rate.

And Lisa will testify that this trip to Wisconsin became very important because of the fear of not knowing what would happen to her next. In her mind, this might be the last time she was going to see a lot of these people that she went to see.

Her cardiologist who cared for her agreed she should go on this trip. He suggested that they plan out every hospital on the way, or at least know where it is when they are there, and that is what Mark Hyde did. They went on this trip together and planned out the hospitals on the exits on the way on the trip, and she visited with her family.

In August she was able to go in and see Dr. Kuo. And I understand this is kind of small. But this was his note: After conducting her own research online, Ms. Hyde discovered the Stanford IVC Filter Clinic. She arrives today with her husband, Mark, and they drove eight hours yesterday from Las Vegas, Nevada, to pursue a complex filter retrieval at Stanford. Her clinical history being an IVC filter and fractured fragment which embolized to the right ventricle, and the operation would be a complex IVC filter removal.

The testimony and evidence will show these filters

were not designed to be retrieved in a complex manner. They were designed to be implanted percutaneously, and if they were to be removed, they would be removed percutaneously. It would not be a complex procedure to go in and then weave into the heart to take out a broken fragment. It was not part of the design.

This next slide is another note that you'll see in evidence from Dr. Kuo with regard to her Bard placement. She was -- had subsequent complications of IVC penetration and a fractured fragment that embolized into the right ventricle. She's here for her complex filter retrieval of a fragment from her right ventricle.

On the next slide, you will see a scan that the expert in interventional radiology testifying on behalf of the plaintiffs will go over. This depicts the fact that it was touching her vertebrae and gave her the explanation, finally, of what that pain was.

This is a film to show -- if you can see, the contrast in the vena cava is that dark column, with it coming outside the vein itself.

And the next slide is actually an x-ray without contrast. You can see the piece that's in her heart, which you can't see on the screen because it's soft tissue. But you can see the procedure that Dr. Kuo put her through in order to retrieve that metal.

And with regard to this issue of product identification and the dispute, the testimony that Dr. Kuo will give is that initially on imaging he called this a Bard Eclipse filter. But his impression after it was removed was that it was a Bard G2X filter. This is the man that took it out.

Now, I've been talking for a long time, and again, it's the last -- first until the last time that we can address you directly. And the rest of this trial and the way that it's going to go, you're going to hear the testimony and the evidence come in, and we come back at the end and we'll talk to you directly again in our closing arguments.

And at that point, I'm confident that the evidence and testimony that comes into this case will support a verdict for Lisa Hyde. And at that point, we will come back and ask you for one.

Thank you for your attention. Again, thank you on behalf of the plaintiffs and Mrs. Hyde and Mr. Hyde for your service on this jury today.

THE COURT: All right. Thanks, Ms. Reed Zaic.

Members of the jury, we're going to take the afternoon break at this time before we hear the defendants' opening statement.

So we will resume at a quarter after. Please remember not to discuss the case. We'll excuse you at this time, and you can head out this way to the jury room. We'll see

everybody at a quarter after.

(Recess taken, 3:01 p.m. to 3:15 p.m.)

THE COURT: Mr. Rogers, you may continue.

MR. ROGERS: Thank you, Your Honor.

May it please the Court, and ladies and gentlemen of the jury. My name is Jim Rogers, and I along with Ms. Helm and Mr. Condo are honored and privileged to represent C.R. Bard in this case.

Now, I expect that you --

THE COURT: Sorry, Mr. Rogers.

We're still getting static.

MR. ROGERS: Oh, I'm sorry.

THE COURT: We frisked the jury during the break, and we know it's not their problem. Somebody has your phone on. Please, everybody, turn them off. Don't just put them on airplane mode. Turn them off.

Let's wait for a minute, Mr. Rogers, until that happens, and that way you won't get interrupted again.

MR. ROGERS: Thank you.

THE COURT: All right. Go ahead, Mr. Rogers. Sorry for the interruption.

MR. ROGERS: No problem. Thank you, Your Honor.

I expect that you have heard some things during the presentation from Ms. Zaic this afternoon that caused you concern. And you may be asking yourself right now, I wonder if

IVC filters are a good idea. I wonder if they're safe.

I submit to you, ladies and gentlemen, that what you've heard this afternoon so far is just part of the story. And there is a completely different side of this story, a story that will be more whole and more complete than what you heard earlier this afternoon.

And at the end of all the evidence that you're going to hear in this case, you're going to be asked to decide one essential question, and that is, did the benefits of the IVC filter that was implanted in Mrs. Hyde -- and that benefit would be to potentially prevent a life-threatening pulmonary embolism -- did it outweigh, did those benefits outweigh the potential risks of an IVC filter?

And I will submit to you that the evidence is going to show that there certainly are risks, and we're not going to try and tell you that there's not. But I'll also submit to you that the evidence is going to show from both sides, when you hear experts and witnesses, that these risks of these filters were well known and well understood, and doctors were willing to accept those risks in order to treat their patients.

And I also submit to you, as you hear all the evidence, that ultimately you will come to the conclusion that Bard is wrongfully accused in this case. Because the benefits of the IVC filter that was implanted in Mrs. Hyde indeed do outweigh those risks.

Now, it's my job this afternoon to try and give you a little bit of a road map about where we're going and try to summarize the evidence that you're going to hear over the course of the next two and a half weeks, so I know that's a long road that you see a map for. But I want to talk to you about four primary things.

First, I want to talk about the defendants, C.R. Bard. And that's not just a nameless, faceless corporation. It is comprised of people who are engineers, regulatory professionals, and scientists, who go to work every day just like you do, and they put their skills to work in order to bring medical products to the market so those products can be put in the hands of doctors so those doctors can then improve the health and lives of their patients.

I also want to talk to you about the device, the IVC filter. And I expect that when you came into court today, a lot of you had never heard of an IVC filter and didn't know what it was. But what I want to talk to you about is, first of all, the disease state, pulmonary embolism, what IVC filters are intended to prevent.

And then I also want to talk to you about the efforts that Bard has made over the years to develop these products, to put them on the market, and continue to innovate over the course of time to make these products better and better year after year.

And I'm also going to talk to you about the plaintiff. Now, of course, there's two plaintiffs in this case, both Mr. and Mrs. Hyde. But the person I'm going talk to you about today is Mrs. Hyde. And really, what I want to speak to you about is her medical history and background and why her doctors believed that it was critically important that she receive the maximum protection from a potential pulmonary embolism as possible.

And lastly, I want to talk to you about the plaintiffs' burden. You heard some discussion about this during jury selection this morning. But as the individuals who have brought this case against Bard, the Hydes do bear the burden of proof in this case, and I want to talk to you about that and I want to talk to you about the legal hurdles that the Hydes have got to prove to you in order to recover in this case.

But first of all, let's talk about the defendants. As you see from this photograph, C.R. Bard is a company that's been around for a very long time. It's over a hundred years old. And the gentleman you see here is Charles Russell Bard, and that's who C.R. Bard is named for and the founder of the company.

And he worked with a doctor named Dr. Foley way back when in order to invent a catheter called the Foley catheter. And it's been around now for a hundred years, and it's still

used in hospitals today.

And of course, you know, things didn't stay stagnant like you see in this picture, but Bard has continued to evolve over the years. And today, C.R. Bard is a large corporation that is based in New Jersey. And it's got multiple divisions that make all kinds of medical devices, including products to be used in the vascular world, urology, oncology, and surgery.

But the division that we're going to talk about the most is the peripheral vascular division, and that is the division that makes IVC filters for Bard. And that company is located right here in Phoenix, in the Phoenix area. It's in Tempe.

And that company focuses on primarily two different types of products. First of all, vascular products. That means products that you're going to use in your veins. And to give you some examples of that, you see up on the screen now there's a stent. And that's something that you put inside of a blood vessel to hold it open if it's become closed or clogged.

And in the bottom left-hand corner, you see what are known as catheters, and those are Power catheters, so doctors can inject a dye called contrast into the veins of a patient so that they can see what's going on inside of their veins.

And then Bard also makes -- and Bard Peripheral Vascular makes products that relate to oncology; in other words, the treatment of cancer. And they make a number of

biopsy products that help diagnose those kind of conditions. And they also make these products that you see up there called ports, which are surgical ports. And those are used in patients who have to receive medication long term, where you have to have access to people's veins. Something like chemotherapy. And those ports are put into a vein so that the doctors can run the drug through the port and not continually stick the patients over and over again.

But most importantly, you're going to meet real people. You're going to meet employees from Bard who are these engineers and regulatory professionals, and you're going to get to hear their stories in this courtroom of their work to bring these products to market and how they continually strive to improve these products over and over again. And you'll get to judge these folks for yourself.

The next thing I'm going to talk to you about is the device, the IVC filter. And the first thing I wanted to speak to you about is the disease state. You've heard plenty about this, but I want to talk about it a little bit more.

But deep vein thrombosis is a very serious issue in this country, and as you've heard, I mean, this is blood clots that can occur in the veins in your legs and hips, the lower part of the body. And this can happen, you've probably heard, like if you're taking a long flight, you need to get up and walk around, drink plenty of water so that you don't develop

these clots.

But there's other things that can cause them too. There's certain people that have genetic clotting disorders that they're just naturally prone to develop blood clots. And you can also develop these if you're laid up for a long time, if you've had a surgery that's major or if you've been in a serious accident where you're going to be immobile for a good while. All those people are at risk of developing these clots.

And DVT is a very serious problem that needs to be addressed, but the real thing that we're here for today is pulmonary embolism. And that's a much, much more risky complication. As you can see from the diagram that's up on the screen, that happens when one of these blood clots in your legs breaks off and it swims upstream, up through the IVC, the inferior vena cava, goes to the heart, goes through the heart, and then goes to the lung.

And if one of those clots hits in just the right place, it can completely stop the blood flow in the lung and cause immediate death. And this is obviously a very serious issue that needs to be addressed and prevented.

Now, just a few facts and figures about DVT. A lot of people experience this in the United States. As you can see, it's very high numbers. 600,000 people can be hospitalized a year for that condition, and you also see up here where 200,000 to 300,000 people in the U.S. alone can die from a pulmonary

embolism each year. And 33 percent of people who will have a DVT or a PE are going to experience another one. So it's particularly dangerous for those individuals who have already got a clotting issue.

And you also see up here that the standard treatment for these blood clots is something called anticoagulants. And those are drugs. And they can come in a couple of different forms. You can get them intravenously, and that happens sometimes in hospitals where you get a drug called either heparin or Lovenox. You may have heard of those.

Or they can be oral as well. And the one that was around for years and years was a drug called Coumadin, and its trade name is called warfarin, so they're the same thing, but you probably have heard of both of those.

And there's also a lot of new-generation anticoagulants that are on the market now that you probably have seen ads for on television, like Xarelto and Eliquis. And those are very effective treatments for blood clots, but certain people are either contraindicated from taking those drugs, meaning that they've got a potential issue to bleed themselves, and you don't want to put somebody who's got a bleeding issue on a blood thinner; or there's other people who might be fine taking a blood thinner but they have to come off, you know, to have surgery or something like that. And at that point, they don't have any protection from a clot.

And with some of these individuals, that's really where IVC filters come in, is when somebody's either -- the drug is not effective, it doesn't work, or if they have got a situation where they need to come off and then they can be restored to the anticoagulant later on.

But you heard some reference to this during Ms. Zaic's presentation. And this was a document that was published in 2008. And as you heard, this was put out by the Surgeon General, and it's a report, but the Surgeon General at the time did not call it a report. He called it a Call to Action.

And as you can see from the callout that we have up there, the Surgeon General felt that these issues, which are critically important and which cost the lives of so many Americans, are kind of under the radar screen. And you can see for yourself that the Surgeon General pointed out that very common things that we're all very familiar with, car wrecks, AIDS, breast cancer, those issues do not cause as many deaths as DVT and PE.

And so the Surgeon General found the status quo, as he calls it there, unacceptable and wanted to get more information out about what to do with these very serious medical conditions.

And two of the things that the Surgeon General includes in this report as effective treatments for DVT and PE are anticoagulants and IVC filters, including retrievable IVC

filters, which you're going to hear more about in a moment.

Now, what is an IVC filter? Now, you heard some about this, obviously, already. And up on the screen you have pictures of the G2X and the Eclipse filter.

But I first want to show you kind of where those go. And you may have gotten a sense of this from the earlier animation. But as you can see, the IVC filter is implanted right there in the inferior vena cava, and it's put usually right where the veins from the kidneys are flowing into the inferior vena cava.

And the reason for that is, is when one of these filters catches a clot, it will kind of sit there. And this blood that kind of rushes in from the kidneys washes over the clot and just naturally breaks it up. And so it can then shrink to a size where it is not dangerous, or it just dissolves completely.

And I'm going to show you a little animation here -- I've got to have an animation, too -- of a filter catching a clot.

And here you see the clot traveling up the IVC. It hits the filter, and its blood flow continues to go around it. The clot will ultimately break up and dissolve.

Now, let me pick up with Bard's story about IVC filters. And as Ms. Zaic indicated, kind of the story sort of starts in 1990. And you've got a picture here of a filter

called a Simon Nitinol filter. And that filter was not developed by C.R. Bard, and it entered the marketplace in 1990. And the company that put it there was called NMT, which stands for Nitinol Medical Technologies.

But then later, in the early 2000s, Bard purchased the rights to that filter. But they also purchased the rights to another filter, the Recovery filter, which NMT had under development at the time. And that was going to be a big deal, because that filter was going to be a retrievable filter.

The Simon Nitinol filter and all filters that came before that were permanent filters. If they went into a patient, they did not come out unless you removed it surgically. And that really limited the patient population that doctors could use with those filters, because they could only put them into people that they knew would need them for really long term, for the remainder of their lives. And so they primarily got used in terminally ill patients, the very elderly, folks like that.

But the retrievable filters kind of revolutionized that world, and I'm going to talk to you a little bit more about that in a minute. But first I'm going to continue this sort of timeline of these IVC filters from Bard.

In 2003, Bard introduced the Recovery filter. And then in August of 2005, Bard made its first second-generation filter, the G2 filter. And they learned from their experience

with the Recovery filter on how they could potentially improve that filter, and they made improvements to it. And we'll talk about those.

And then a few years later, Bard introduced the G2X filter. And as you can see, I put in parentheses there G2 Express, because you may see documents through the course of the trial that say G2 Express. But G2 Express and G2X are the same thing. I mean, they're completely synonymous, and I just wanted to flag that for you.

But that filter added a hook on the top of the G2 filter. And then in January of 2010, Bard introduced the Eclipse filter, which was electropolished. And we'll talk about what that means in just a moment.

But first let's talk about retrievable filters. And as I indicated, this was a really big deal, because these filters were just permanent. You know, way back when, when they first started doing this like in the '40s, you know, patients had to be actually opened up surgically and the filters implanted and sewn in and then sewed back up.

But as they continued to evolve and make strides in technology, these filters could be put in what we call percutaneously. In other words, you could make just a small incision either in the jugular vein or your femoral vein and run a catheter through there and put these filters in, and that's what the Simon Nitinol filter was. But it was only

indicated for permanent use.

But there did start to be some what were called retrievable filters, but they were indicated for only very short periods of time. So they were available to a doctor, but they could only stay in for, you know, up to about two weeks or so. And if that wasn't an option and if the patient needed protection longer than that, the filter still needed to come out.

And some of these filters actually had a tether on it, so that when they got put in, I mean, there was a wire that literally stayed out of the patient for the filter to be retrieved.

But ultimately, these retrievable filters came out, and those allowed doctors to be able to put these in and take them out much, much easier. And these filters could stay in patients for much longer periods of time, or at least some of them could.

And the Bard retrievable filters, when they first came into the market, they did not have a specific time period by which they had to be removed. They could be put in and kept in at the discretion of the physician.

And so this is really beneficial to patients that only needed temporary protection from an IVC filter. So if you've got a patient who's doing fine on anticoagulants but all of a sudden they need to have surgery, so they have to come off the

anticoagulant, then you can put one of these temporary filters in. And then once that surgical period is over and the patient is reestablished on their anticoagulant, you can take the filter out. So that gave a different option to what doctors could do.

And you heard some about this Nitinol. I mean, that is what the Bard filters are all made out of. And I certainly, before I got involved in this, I'd never heard of that. But it was developed by Navy scientists in the 1960s, and it really is kind of interesting because this particular metal has what is called shape memory. And so when it is originally forged into a shape at a certain temperature, the filter or the product, whatever it is that's made of Nitinol, will remember that shape.

So you can take this and forge it and then keep it cold, and it will stay in a certain shape. And then you can twist it up and do whatever you want to, and if it's cold, it's going to be -- retain whatever shape you put it in. But if it's exposed to a warmer temperature, like when it gets into the actual interior of the body, the filter will remember, or a product made of Nitinol will remember what shape it was originally forged in, and it will kind of immediately just return to that shape.

And I'm going to show you an animation of kind of the implantation of a filter so that you can see this.

But as I mentioned a moment ago, you can either do a jugular approach or a femoral approach. And with the Bard filters, you can do either. With certain filters, it's limited to one or the other.

But what you're going to see here is a femoral approach. In other words, this is going to be a situation where the doctor would have made a small incision in the leg and then is running catheters and wires up through the leg into the IVC. So I just wanted you to have that orientation of what this was like.

All right. The first thing you see, that's a guidewire. That's the first thing that goes in, and then a sheath goes over the guidewire. And the sheath gets pulled back. And then the catheter that has got the filter on it is put in, and as soon as that catheter is pulled back, the filter springs back into shape because these Nitinol filters understand and remember what shape they were supposed to have.

And this is just a little bit different angle. And there's the filter, catheter comes back, and the filter springs into shape.

And along those same lines, I want to show you an animation of a retrieval. And retrievals, unlike the implantation of a filter which can kind of come from either the jugular or the femoral -- with the Bard filters, it has to come from the jugular direction because those are the -- you know,

it's got the hooks on the top, and that's what you have to kind of catch.

But you'll see here how this works. First, the guidewire is going to come down and run through the filter. And then a catheter is going to follow. And this is using a little device called the recovery cone. And it is going to open up like an umbrella and then grab the tip of the filter, and then the doctor pulls it back. And the filter will dislodge from the cava and then go back up into the catheter where it can be retrieved.

Okay. Let's talk a little bit about the Recovery and the G2, and you heard some of this in Ms. Zaic's presentation. And the Recovery was the first-generation retrievable filter. Now, I need to spend some time on this, even though these were not the products that Mrs. Hyde received.

And based on this experience with the Recovery filter, Bard did learn. And what happened was when the Recovery filter was out there, Bard did receive complaints or reports of things that were occurring. And the thing that was the most concerning, you heard Ms. Zaic talk about this, was what is known as cranial migration or cephalad migration. And as she told you, that is migration when the filter moves up toward the head or toward the heart. And that's really something you want to avoid.

And so based on that experience, Bard made some

dimensional changes between the Recovery and the G2 to prevent that as well as to try and prevent additional fractures. And as you can see here, I mean, you can -- it's not that hard to see, but the arms of the filter got made longer and a little bend got put in them, and the span of the legs got made a little wider. And then you can also see the hooks -- it's kind of hard to tell here, but they got made a little longer and a little stronger. And all of that was to try and bring more stability to the filter.

And the evidence is going to show that these things worked. I mean, they helped. And Bard's own internal testing will show that the G2 filter, which you hear called the G1A -- everything's got two names in this case, so I apologize for that. But the G2 filter compared to the Recovery filter did have better fracture resistance, and it also did better with migration resistance.

But importantly, this is not what this case is about. These are the early generation filters, and neither one of those filters are the filter that's in Ms. Hyde. There's no dispute about that. We know that.

And I'm going to talk a little bit more about Bard filters as they continued to innovate. You see there the G2 and the Eclipse, and you heard something about this too. But after Ms. Hyde's filter was put in her in 2011, there were additional filters that came on the market. And the one you

see here on the left is the Meridian filter. And that added some additional anchors to try and keep the filter, again, more stable within the cava and to prevent it from moving down, from migrating caudally, and that's the direction toward the feet.

But that filter was not on the market when Ms. Hyde got her filter. It was still being tested, and it had not yet been cleared by the FDA. And the filter that's on the market now, the Denali filter, is really quite unusual. Before the Denali filter, all of these filters were made by various component parts that were welded together. But the Denali filter is made from one piece of Nitinol. It's forged out of one single thing, so everything about that filter is all one piece.

And at the time Ms. Hyde got her filter, this was completely in the development stage, and it did not get introduced into the marketplace until 2013.

So this case is not about these subsequent filters, and it's not about the prior filters. And what this case is really more about are the G2X filter -- which you see here, and you can see the difference where the G2X has got the hook on top. And that allows the doctor more options to try and retrieve the filter -- and then the Eclipse filter. And that added electropolishing, and you heard a little bit about this. And this process, electropolishing, really smooths out the surface of the filter.

And that's some photographs that were taken with an electron microscope. I mean, this is the kind of level we're talking about. But you can see that prior to electropolishing, there were some imperfections in the surface of the filter, and those are things that potentially could be the source of a fracture. So electropolishing was added to try and reduce fracture even more.

Now, you've obviously heard something about this. I mean, what is the filter in Mrs. Hyde, or that Mrs. Hyde had in her at the time? Of course, it's out now. And the real answer is nobody knows, and this is really weird. I mean, this is a very unusual situation for a case, because usually everybody always knows what product is in a patient.

But there's several sources of potential information that might shed light on this, and I'm just going to go through them with you and tell you what we think the evidence will show on them.

First of all, the filter has a hook, so we know it's not a Recovery or a G2. And we know that based on the imaging that was taken of the filter, the x-rays and the CT scans that were done of Mrs. Hyde's filter when it was in her body. So you will see those yourself, and you can look at it, and you will see that it's got a hook on it. So that completely eliminates the possibility of it being a G2 or a Recovery.

But even though those x-rays will tell us that it's

got a hook, if you look at the G2X and the Eclipse under an x-ray, they really look exactly the same. Dimensionally, they are really pretty much -- there's no difference. And you're not going to hear a witness that is going to come into the courtroom and tell you that "I can look at these images and tell you that this is a G2X or an Eclipse filter."

When Mrs. Hyde went to Stanford and had the filter removed, it was not retained. That's obviously another source that you could have, but Stanford disposed of the filter. And I'm not ascribing any fault to Mrs. Hyde because of that. I mean, Stanford just didn't keep it. So if the filter was still around, it could be inspected and we could figure out what filter it was, but it just doesn't exist anymore.

And then medical records, as you may have picked up some from Ms. Zaic's presentation, they call it G2X, they call it G2, they call it Eclipse. So it's kind of all over the place.

And usually when these products are implanted, you know, when the kit comes for the doctor to open up and use, there's a sticker that can get peeled off of the material that comes with the product, and it gets just stuck right there in the medical record. And that's usually what we always use to know what product it was.

But in this case, again, through no fault of Mrs. Hyde, that doesn't exist. We don't know why. Just for

whatever reason, in the records from the hospital where the filter was implanted, there's no sticker. There's no lot number. There's no real identifier of what this filter is.

And you're also going to hear the testimony of her treating doctors. You heard some about Dr. Henry. He's the doctor that put this in in Wisconsin. And you heard about Dr. Kuo, who was the doctor who took it out in Stanford. And I want you to listen very carefully to their testimony. They won't be here live. You're going to see both of them by what we call depositions, but it's a video deposition, so you'll get to see what they look like.

And you'll hear both of these doctors tell you that "Sitting here today, I can't tell you what filter this is." So listen carefully for that, and make those decisions for yourself.

But there are some records that we think provide some circumstantial evidence of what this filter is, and these are billing records. I mean, this is -- you know, we're kind of hitting the bottom of the barrel here as far as these types of evidence. But I did want to tell you what we've got.

And this is a chronology that kind of lays some of this out. And let me go through this with you, but I'm going to start you with February 25th, 2011, just to kind of orient you, because that's the day that Mrs. Hyde got her filter.

And then -- and as you see, Mrs. Hyde's filter was

placed by a jugular approach, so her doctor, Dr. Henry, went in through her neck. And we can tell that from the medical records, so that we know that the kit that got used was a jugular kit. So that's what we're looking for is a jugular filter.

And so if you go back up to the top, in October of 2009, that's when the G2X came on the market, about 18 months before Mrs. Hyde received her filter.

And then in January of 2010, the Eclipse came on the market. So it had been on the market for a little more than a year when Mrs. Hyde got her filter.

Now, we know that the last time that the hospital where her filter was placed, when -- the last time they ordered a G2X filter that could be used from a jugular approach was in January of 2010. So if this was a G2X, it sat on the shelf for more than a year before it got used on Ms. Hyde. And I'm not telling you that's impossible, but that's what would have had to have happened.

And then you see in these sort of interim dates, those are dates when the hospital ordered Eclipse filters. And from November to January the 12th, there were six different filters that were ordered, but they were all femoral filters. So we know that none of those filters were used in Ms. Hyde because she got a jugular filter.

But on February 23rd, two days before Mrs. Hyde's

procedure, a filter -- an invoice was done by Bard to the hospital for a jugular filter, an Eclipse filter, and a femoral filter as well. There were two that day. But those filters were shipped out from C.R. Bard to the hospital for two-day delivery FedEx, and we know that the filters arrived the morning of Mrs. Hyde's procedure. And we also know from the medical records that Mrs. Hyde's procedure did not start until about 1:00 in the afternoon.

And then one other fact to be aware of is that after her procedure was done, a few days later, on March the 1st, 2001 [sic], the filter ordered -- excuse me, the hospital ordered another jugular Eclipse filter. And I submit to you that that is some circumstantial evidence that the hospital was replacing the jugular filter that was used in Ms. Hyde, the Eclipse filter. But again, we don't know; but I do think this is some circumstantial evidence that the filter used in Ms. Hyde was an Eclipse filter.

But at the end of the day, as far as Bard is concerned, we don't think it matters. Both of these filters were really good filters. And importantly, these are rates that Bard uses to track complications and things that occur with its products. I mean, that's something they do on a routine and regular basis.

And you heard Ms. Zaic talk about this some, but, you know, when reports come into Bard from various sources, from

doctors or hospitals or an individual, Bard is obliged to keep up with that information and provide that to the FDA. And so as part of this process, Bard does these trending numbers. And what they do, they take the number of complications that are reported to them and compare that to the sales of that product, and come up with these rough rates about what are the complication rates that Bard is being -- receiving from the field.

And as you can see, for the G2 Express and the Eclipse, these rates continue to trend down from the prior filters. That first column you see is -- the RF, that's the Recovery filter. And then the next one is the G2, then the G2 Express and the G2X, one column, and then the Eclipse. And over the course of time, these numbers come down. And that's what's important to Bard, that the improvements that they're making to these products are working.

And there are the numbers that Bard has for reported rates for some of the things you've heard about that can happen with filters, some of these complications for fracture, migration, perforation, and tilt.

And to look at these numbers in a little bit different way, you know, this means that for the G2X, that as far as the reported amount of complications that's coming to Bard, you know, it's almost a hundred percent of -- slightly over 99 percent of the filters that they're selling, they're not

hearing back reports of complications.

And with the Eclipse, that is -- numbers get a little bit better.

Now, I'm sure you're going to hear evidence during the course of the trial that these numbers are not that great. I mean, that these are subject to criticism. And Ms. Zaic talked about that some in her presentation. She talked about underreporting, that all the things that happen with these products don't get reported.

And Bard does not dispute that. I mean, that's real. That happens. And busy doctors are not going to report every single complication they see.

And -- but this is a very important part of Bard's story, because this is something that they do ongoing, constantly, to try and see what these numbers are doing and how they're trending and are they getting better. And that's the important thing. And we're not here to tell you these numbers are perfect, but they are some information that Bard relies on based on its internal information.

Now, next I'm going to talk about the plaintiff, Mrs. Hyde. But before I do, I need to tell you that the last thing we are here to do is to criticize Mrs. Hyde. And we do need to talk about Mrs. Hyde, because I think her medical history is very important to this case, but we all feel sympathy for her. I mean, she went through an ordeal, no

question. I mean, she found out she had a piece of metal in her heart. Nobody wants to hear that.

But even though we're human and we feel sorry for her and feel sympathy for that situation, her overall medical history is very important to this case. And there's some things that I want to address with you.

And here's the timeline, and I hope you can see that -- those points on there, because they're a little bit small. But in the late 1980s, Mrs. Hyde experienced her first PE. And that was a point in her life when she was younger and she was taking birth control pills. And there's a known association between birth control pills and blood clots. And so at that point in time, that's what that clot was attributed to.

Then you fast-forward many years later to February of 2009, and Mrs. Hyde experienced another -- a second PE and a DVT. And standard therapy is to receive anticoagulants. First when she was hospitalized for that, she received intravenous anticoagulants like we discussed earlier, and then when things were a little better, she was discharged but she continued to take oral anticoagulation for a standard period of about six months.

That's usually what happens, and if you don't have any clotting issues for about six months, your doctors will usually take you off those medications. And that's what happened with

Mrs. Hyde.

But then in February of 2011, almost two years exactly from when she had the DVT and the PE in '09, Mrs. Hyde developed another DVT and PE. And this was quite a large pulmonary embolism in her lung, and in fact, she had a pulmonary embolism in both of her lungs, both her right lung and her left lung.

And the one that was on the right was really quite large. And her doctors really kind of went immediately back into that same treatment mode, where she receives intravenous blood thinners in order to try and treat those clots.

But this time, because of the proximity of this event to the prior event just two years before, an interventional radiologist named David Henry was called in to assess whether Mrs. Hyde should receive an IVC filter. And it was Dr. Henry's medical judgment that she needed as much protection as possible while these anticoagulants were getting up to speed and starting to work in order to protect her from PE.

And you'll also hear that Dr. Henry specifically wanted her to receive a retrievable filter. And that's what he did, and he implanted that filter on February the 25th at this hospital in Wisconsin.

Next day, the doctors are doing some more testing on Mrs. Hyde, and that is when it's determined that she has got this clotting disorder called a protein C deficiency. And that

means, unfortunately for Mrs. Hyde, that she is going to need to take anticoagulants for the rest of her life. And hopefully that will all go very, very smoothly.

And so when she was discharged at this period, she ultimately was taking Coumadin for a period of time, and then later she switched to one of the newer generation anticoagulants, a drug called Xarelto, and she's still taking that drug today. And Mrs. Hyde sees the doctor on a regular and routine basis multiple times a year in order to check her for -- to make sure that everything's going okay on those anticoagulants.

But as Mrs. Zaic discussed in her presentation, in August of 2011, the Hydes moved from Wisconsin to Las Vegas so that Mr. Hyde could pursue a new job in Las Vegas. And I just again orient you, just like she did, that at that point in time we shift from medical care in Wisconsin to medical care in Nevada.

And so several years later, as Ms. Zaic indicated, Mrs. Hyde was being worked up in May of 2014 to see if she had a kidney stone. And as part of that, a CT scan was done, an imaging study, to see if she had a stone. And the doctor that read the images from that CT scan noticed what he thought was a piece of metal in her heart. And as Ms. Zaic indicated, this was an incidental finding. Nobody was looking for this at the time, but the doctor was smart enough to pick up on it.

And so they did some confirmatory imaging after that and realized that this was a piece of the filter. One of the struts, an arm of the filter, had broken off and migrated to her heart and ended up in her right ventricle.

And as Mrs. Zaic indicated, Mrs. Hyde did do her own research, and she found a doctor in Stanford that she wanted to go see to see if he could remove the filter and the strut from her heart. And that's the decision that she made. And as Mrs. Zaic indicated, she could not get an appointment with him until August of 2014. And in the interim, she did see a doctor named Richard Shehane, who was a cardiologist in Las Vegas.

But ultimately, the Hydes did travel from Las Vegas to Stanford, which is in Palo Alto, California, and they saw Dr. Kuo on the -- you know, one day. He -- she was admitted to the hospital the next. He did the procedure.

And as you can see on the timeline, the total time to remove both the filter and the strut was about an hour and a half, and then she was discharged from the hospital the next day.

Now, those are kind of facts that are very basic that I think everybody sort of agrees on. But the evidence will show those facts. But there's certain things we're probably going to have some dispute about, and so I'm going to have to ask you jurors to put your medical detective hats on.

And when I first started as a lawyer, you know, the

medical detective that everybody identified with was Quincy. And we've got jurors here who I'm sure have never heard of Quincy and have no idea who he is. So I included some other once. We've got Dr. House, and then we've got some of the people from -- Abby Sciuto from NCIS and Loretta Wade from CSI New Orleans. There's so many CSIs, I can't even keep up with them anymore, but that's the one she's from.

But what you're going to get a chance to do is to see Mrs. Hyde's medical records yourself. And you're going to get to make determinations based on your own experience, your own judgment, about what you think those records show.

And as you go through those records, and you heard Ms. Zaic allude to this, I want to talk about two specific periods. First of all, February 2011 to August of 2014, and that was the period of time when the filter was in Mrs. Hyde's IVC. And you may hear claims in this case that it was causing things like abdominal pain, the filter itself, and back pain from where it was interacting with other organs.

But as you see these medical records and you hear the testimony, I want you to ask yourselves, were there other things that were going on that might attribute to these things that Mrs. Hyde was experiencing. And be on the lookout for things like: Did she indeed have a kidney stone? Did she get diagnosed with endometriosis? Did she have to have surgery for that? Did she get diagnosed with diverticulitis and get

treated for that? Does she have degenerative disk disease, and if she does, when did that start and what kind of issues can that cause? And was she diagnosed with something called fibromyalgia, which is a generalized pain disorder?

And again, you're going to have to sort through all those things yourself.

And you also may hear claims about -- during this time period about chest pain and chest palpitations that perhaps may be attributed to the strut that unfortunately wound up in Mrs. Hyde's right ventricle. And when you hear evidence about that, ask yourself, when did those things start? And when did they stop? And were there other things that were going on that perhaps might cause those particular types of conditions?

And again, that is your decision as the jurors.

Another important time period is going to be September the 14th to September the 18th [sic]. And that's the four-year time period that has elapsed since the filter and the strut have been removed from Mrs. Hyde by Dr. Kuo at Stanford.

And you may hear evidence in this case that Mrs. Hyde may be at risk of certain heart conditions because of the strut that was in her heart. And so you may want to ask yourself things like, has she been under the care of a cardiologist since Dr. Kuo took the strut out of her heart? And if she was admitted to the ER in February of 2016, did she get a full cardiac workup at that time? And if she did, were certain

tests done? And what did they show?

And again, that's going to be things for you to look for and you to make your own decisions about.

And there's going to be another important medical detective aspect of this case, and that is these complications. And you've heard some about that. Tilt. Caudal migration, migration down. Perforation. Are parts of the arms or legs of the filter, are they poking outside of the inferior vena cava?

And you're going to get to see the imaging yourselves. And experts from both sides will probably talk to you about that imaging and tell you what they think it means. And these are people that are very smart that have been to medical school, and they know a lot. But at the end of the day, you're the people that decide those issues. And you'll be able to view those images yourself, and you'll be able to decide, do I think that this filter tilted? Do I think it caudally migrated? And if it did perforate, what did that mean?

And again, those are things you're going to have to look for and come to your own conclusions.

All right. Last thing I'm going to talk about is the plaintiffs' burden, and it's going to take a while. I realize that sounded like I was going to wrap up, so I need to at least be honest with you.

But Mrs. Hyde is asserting an alleged defect case, the design defect. You heard about that. We're going to talk

about that. We're going to talk about causation. And then last thing, I'm going to talk about damages.

But first of all, let's talk about design. And that gets back to sort of where we started. That's the issue of did the benefits of this filter outweigh the risks of this filter. And that's really what is a critical question in this case.

And I submit to you that the evidence is going to show that the benefits are quite substantial. If you have a recurrent PE, you have up to a 30 percent risk of death from a subsequent PE. And Mrs. Hyde was on her third PE, unfortunately, when this filter was placed in February of 2011.

And even though anticoagulants provide very good protection from blood clots, those products are not without risks. And you may have heard about some of this. But anticoagulants, both the intravenous kind and the oral kind, come with risks, and primarily it's risks of significant bleeding. They don't cause bleeding, but if you happen to have a bleed, the bleeding can obviously be much worse if your blood has been thinned.

And particularly, one of the biggest issues there is if you have a hemorrhage in your brain and you have a stroke, that can be potentially fatal or cause permanent damages. So those products are not without risk.

But what you're going to see is that of the patients who receive a Bard filter, according to Bard's internal data,

very, very few of those patients report experiencing a pulmonary embolism when a filter is in place. And again, I'm not here to tell you that filters are a replacement for anticoagulants. That is really kind of the gold standard where doctors typically go to in order to treat these conditions. But filters are an excellent treatment for doctors that they can use instead of anticoagulants if it's the right patient.

And so why do they do that? Why do doctors do that? I submit to you that's because the doctors realize that these filters have the benefit of potentially saving a patient's life from a deadly pulmonary PE. And they realize that there are risks that come with these products, but they're willing to accept those risks and advise their patients about those risks in order to give them the protection they need against pulmonary embolism.

All right. Let's talk a little bit about the design challenges. And you're going to hear some of the Bard witnesses talk to you about this yourselves. But as Ms. Zaic indicated, the IVC is a very dynamic environment. There's a lot of forces that are going on. And when you design a product in order to be put into the human body, you have to have a lot of different considerations at play.

And as you can see from this, I mean, this shows the IVC, the blue one, the inferior vena cava, the venous side, and then it's next to the aorta, which is the red one, the arterial

side. And of course, in this cartoon, you know, these things are straight up and down like a tree trunk kind of. And, of course, you know as well as I do that that's not the way people are. I mean, people are continually moving in all kinds of different ways. We're not walking around, you know, like trees. So there's a lot of forces that are obviously exerted from time to time on the inferior vena cava.

And people also do things like cough. You know, you have what's called a Valsalva maneuver if you put pressure down into your abdomen, and that can also increase the stresses in that environment. But all of those things have to be considered, and you're going to hear the Bard people talk about that.

And as you're designing these products, it's kind of a continual trade-off as well, and that's what the evidence is going to show through the Bard witnesses. When you design a product that is intended to go in the body and then to be retrieved percutaneously, you have to have some considerations as to what are going to be the design attributes that are going to allow the filter to be put in the body, remain there, and be effective, but also to be retrieved later on.

And you can strengthen all of the various parts of the filter. You can make the legs more strong. You can use thicker metal. You can make the hooks stronger. You can use thicker hooks. But all of that means that you're one step

closer to this filter either being very difficult to retrieve or perhaps not possible to be retrieved.

So those are all design considerations that you're going to hear about from the folks at Bard.

Ms. Zaic talked about this, too, briefly, and this is something you're going to hear about. The Society of Interventional Radiologists, that is an organization that is comprised of the doctors who are primarily the people who do procedures to put these types of products in. And in 2001, this document was pulled together by a gentleman named Clem Grassi or Clement Grassi. And you're going to see him testify in Bard's case.

And Dr. Grassi led this effort to try to get a working group within this organization to basically cull the medical literature and try and pull together the information that was available in the medical literature about what types of rates of complications are being seen with IVC filters.

And this was not about Bard's IVC filters. This was about IVC filters in general. And when this was first published in 2001, Bard's retrievable filter had not even come on the market yet. The Recovery was not on the market, so all this data was about the filters that were permanent filters.

But you'll see that they put this chart together that appears in this article, and this is some of the information that they found, that with IVC penetration, you saw rates from

0 to 41 percent. Migration, you saw 0 to something. I can't see it. You have to forgive me. I hope you folks can. And then for filter fracture, the rates they saw were 2 to 10 percent.

And so that was information, again, that was available to the medical community and was an important data point for people involved in the IVC filter world to be knowledgeable about and cognizant about. And again, you're going to probably hear criticism from the plaintiffs that this is not intended for IVC filter manufacturers.

We do not disagree. That was not what it was intended for. But again, if you are a manufacturer of an IVC filter, I submit to you this is important information for you to be cognizant of and to be aware of.

All right. The design process. And again, I think you folks know that, you know, you can't just snap your fingers and put a filter on the market. There is a regulation that process -- regulatory process, excuse me, you have to go through through the FDA. And as you heard, these products have to be what is called "cleared" in order to enter the marketplace.

And this story kind of starts, again, way back in the mid-'90s. And, you know, before this period, IVC filters were what were known as a Class III medical device, and that's the class that most implantable devices fall into. And if you were

a Class III device, you have to go through this process that Ms. Zaic talked about called a premarket application, and it is quite a rigorous process, and submit that to the FDA.

But in 1996, the FDA started looking at IVC filters, and they were analyzing whether they should do what is known as down-classify IVC filters. In other words, move them from a Class III medical device to a Class II medical device, which requires less regulation and is not as rigorous in order to put it on the market.

And so this is an internal memo from FDA that you'll see during the evidence here. And you'll see that FDA looked into IVC filters and decided that the risks that those filters can cause are potentially life threatening, they realized that, but they also looked at what the rates were that they were seeing in the medical literature, just like the Society of Interventional Radiologists did, and that was included in this memo.

And ultimately, the FDA determined, because pulmonary embolism is such a serious clinical issue, that they determined that filters do not present an unreasonable risk of illness and injury. And they moved IVC filters from Class III to Class II. And so at that point, these filters could go through this regulatory process called the 510(k) process.

Now, another document you'll see is an FDA guidance. And that document was published by FDA in 1999. And these

guidances are just what they sound like, they're guidance for people who are in the manufacturing business so that you will know FDA's best thinking about what the FDA expects.

And the FDA publishes things that they expect, if you're going to submit a 510(k) application, should be in the application. And that includes a wide range of testing that they expect you to submit to them.

And as you see here, that's deployment, clot trapping, filter fracture, caval perforation, and migration. Those are all tests that FDA wants to see.

And Bard, in each of its applications, submitted that type of information. But Bard also did more testing than what is just simply required via these 510(k) applications. And you will, unfortunately, get to go through all of this in painstaking detail.

But the G2 filter, for instance, when it was put on the market, there is a list of the types of tests that were done: migration studies, fracture, stimulated use, radial strength, finite element analyses, tensile strength, leakage tests, et cetera. And they also did some in vivo testing with animals, with sheep.

And again, these tests that they performed showed improvement in many categories, including fracture, over the prior-generation filter, the Recovery filter. And so that application for the G2 was submitted to FDA. There was some

back and forth where FDA wanted to ask additional questions, and ultimately, the FDA did clear the G2.

And then the G2 Express comes next, and there's more testing. And they compared the fracture resistance of the G2X to the G2 filter and found improvement. And you'll hear Bard witnesses talk about these tests.

And again, there's multiple tests. Kind of going through this sort of quick, and I apologize. But, you know, that's a test there that they did called flat plate testing where the filter is put in a simulated environment to kind of press it up and down, over and over again, and the filter survived at this point a 77-year test. And you'll see that, and you'll hear a Bard witness talk about that.

And then the Eclipse comes along with the electropolishing, and so there's more testing that's done. And the Eclipse is also compared, as far as fracture resistance, to the prior-generation filters. And in this bench testing that Ms. Zaic talked about, again, there is continued improvement.

And that's, again, comparing it to the prior-generation filters. This particular test showed that it was 77 percent better for fracture resistance.

And this just gives you a little bit of history of the clearances that FDA has given to Bard filters over time. The G2 was cleared on two occasions, once as a permanent indication and once as a retrievable indication. The delivery system for

the G2 was approved on two occasions. The G2X was approved. The delivery system for the G2X was -- I said approved, excuse me. I should correct myself -- was cleared.

The G2X delivery system was cleared. The FDA cleared the Eclipse. And then the FDA also cleared a patient brochure that relates to the Eclipse, and we're going to look at that in just a minute.

But before we leave the FDA story, this is something else that I think is an important piece of this. And in 2010, in August, the FDA issued what is known as a safety communication about retrievable IVC filters. And so this would have been a few months before Mrs. Hyde's filter was implanted.

And as you can see from the document that we have, the FDA directed this -- the audience they directed it to were the medical community that put these filters in and monitors patients who have these filters.

And the FDA doesn't regulate medicine. It regulates medical devices and drugs and things like that, but it doesn't regulate the practice of medicine. So this is kind of an advisory thing that the FDA issued.

And as you can see, below there, the FDA suggested that if you have patients that have retrievable filters and you're following them, and if the indication for why that filter was originally put in is no longer present, in other words, if you're that patient who takes an anticoagulant and

you came off the anticoagulant for surgery and you're able to go back on the anticoagulant, then the indication is now gone. And at that point, doctors should consider removing the filter at that time.

But more importantly, the FDA also acknowledged in this communication to the medical community that there were risks that they knew existed with retrievable filters and that doctors should be cognizant of, and that included all the things you've heard: perforation, fracture, and migration of these products.

Now, you heard Ms. Zaic mention this. This is another part of this case. It's called reasonable alternative design. This is a design defect case. And so part of the burden that the Hydes have is to prove to you that there was a reasonable alternative design. In other words, you can't just say it's defective. There has to be something that would have been a different design that would have either eliminated the risk or reduced the risk.

And I want you to listen to this evidence very carefully, because you're going to hear from a number of people throughout trial who are going to speak to this issue. But you're, again, going to have to decide for yourselves, are the products that -- or product attributes that I'm hearing about, do I consider that to be a reasonable alternative design for the G2X filter or the Eclipse filter?

And ladies and gentlemen, I submit to you that one enormous difference between what you might hear about filter attributes are whether it is a permanent filter, a filter that was only meant to go in and never be removed percutaneously, versus a retrievable filter like the G2X and the Eclipse that could be removed percutaneously. And so listen out for those things.

And also listen very carefully to Dr. Henry's testimony, and listen to see if he says that the filter he put in Mrs. Hyde was a filter that he wanted to be a filter that could be retrieved.

Now, you're also going to see the instructions for use that accompany this product. And this is information that is provided with the product to provide doctors information about the product.

Now, these do come in every single box, and I don't suggest to you that in the OR the doctor is opening the box and pulling this out and reading it and trying to figure out what's going on. I mean, these things are available via the website, many other different sources.

And I also submit to you the evidence will show that most of the things that are contained in here are things that doctors generally already know. But there's nothing wrong with the belt and suspenders to provide this information.

But the information you're going to see about these

warnings relates to the design defect claim. And you're going to have to look at this and see if the information that is in the warning is information that would provide the potential user information that may help them understand the risks and understand the design of the product.

And so to look at this, I'm going to pull out some portions of this. And in both the G2X and the Eclipse filter, this language appears. And it's identical, so it really doesn't matter which one we're talking about at this point.

But there's a section about potential complications. And as you see up at the top, it says: Movement, migration, or tilt of the filter are known complications of vena cava filters. Migration of filters through the heart or lungs have been reported. There have also been reports of caudal migration of the filter.

That was in this instructions for use.

Next bullet says: Filter fracture is a known complication of vena cava filters. There have been reports of serious pulmonary and cardiac complications with vena cava filters requiring the removal of the fragments using endovascular and/or surgical techniques.

That was information that was contained in the instructions for use.

It also says that perforation or other acute or chronic damage of the IVC can occur.

And lastly, it says that filter tilt can occur.

Other portions of this, it does indicate that all of the complications could be associated with adverse events such as medical intervention or death, and it even goes on to say that the risk-benefit needs to be analyzed for everybody patient. You have to do an individual risk-benefit analysis to determine if this is an appropriate device for that patient based on their own individual medical history. And that's up for the doctor to decide.

And lastly, it does note that the standards and guidelines developed by the Society of Interventional Radiologists recommend that patients with filters, both permanent and retrievable filters, be tracked and receive routine follow-up subsequent to the placement of the device.

That's other information that's in the IFU.

And I mentioned this a moment ago. This is the patient brochure that was accompanied -- well, it wasn't accompanied with the filter, but it was something that was available to doctors that they could give to their patients if they wanted to. And this is something that contains in fairly layman language some information about the IVC filter.

And I'm going to pull this section out for you. And as you can see, it says: What are the risks associated with implantable filters? As with all implantable devices, there have been risks associated with vena cava filters. You should

discuss the possible adverse effects of this procedure and the filter with your physician. Potential risks include the following:

The entire filter or pieces of the filter may break loose and travel to the heart or lungs, causing injury or death. You may need to have an additional surgery to retrieve the filter or pieces if they break loose.

And ladies and gentlemen, I submit to you that's exactly what transpired in Mrs. Hyde's case.

And as I mentioned to you earlier, this particular patient brochure was specifically cleared by the FDA.

You did hear some information about the MAUDE database, and that's a database that's proprietary with the FDA that they keep up with. And any report that comes from anywhere to the FDA is put into this MAUDE database as it relates to devices.

And it's probably going to be a disputed issue, but you may hear evidence that Bard's -- the information it provided doctors should have put in comparative rates. In other words, you should tell doctors about how one filter compares to the next.

And if that information is based on the MAUDE database, if you hear evidence about that, I think you should be aware that the evidence will show that right there on the -- you know, the website for the MAUDE database, it says: MAUDE

data is not intended to be used either to evaluate rates of adverse events or to compare adverse events occurrence rates across devices.

All right. Let me speak just really briefly to kind of address some of the things that Ms. Zaic said. And you will hear evidence throughout this case, and I do want to mention it, a lot of the evidence you're going to hear from the plaintiffs, I submit to you, will likely be based on the early generation filters, the Recovery filter and the G2 filter, which we know were not the filters implanted in Mrs. Hyde.

And if we're spending a lot of time in this trial talking about those filters, I just ask you to ask yourself why, when we know that's not what was implanted in Mrs. Hyde. And I submit to you that it will be presented by well-paid experts, but listen, that street's going to run both ways. All the experts that you see in this case are going to be well paid.

MR. LOPEZ: I'm going to object. He's arguing now. He's not really presenting evidence, what the evidence is going to show.

THE COURT: All right. That objection is overruled, but stick to the evidence. And we've got about four minutes, Mr. Rogers.

MR. ROGERS: Thank you, Your Honor. I'm going to wrap it up very quickly.

And also look at documents and see if they're taken in context if you're just seeing snippets and pieces.

And again, I submit to you that the evidence that you're going to see from the plaintiffs is contradicted by the whole story, the complete story, and it's also contradicted by the numbers. And these are these same tracking and trending numbers that I showed you earlier for both the G2X and the Eclipse.

Very briefly, I'm going to talk about causation. That's something the plaintiffs have the burden of. And as you hear information in this case, if you hear claims about these things, again, it's up to you to decide, you know, are these attributable to the filter, to the strut, or are there other issues? And that's your decision.

But it is Mrs. Hyde's burden to prove these things to you, as is it her burden to prove damages. So any information you hear about damages, Mrs. Hyde has got the burden of proof to prove to you that those are damages that should be attributed to the filter.

So to conclude, I'm back to my scales. This key issue is the risk-benefit analysis. Did the benefits of this filter outweigh the risks that were always there and potential with this filter? And I submit to you, as you hear the evidence over the course of this next two and a half weeks, that it will show that the benefits of this filter for Mrs. Hyde outweighed

the risks.

And I think as soon as you see this whole story, you will come to the conclusion that Bard has been wrongfully accused in this case. And we'll come back to you and ask you to return a verdict based on that basis at the close of the evidence.

Thank you very much.

THE COURT: All right. Thanks, Mr. Rogers.

Ladies and gentlemen, we're going to break for the day. We will plan to begin at 9:00 o'clock. If you could please factor in travel time getting here, that would be helpful. I will tell you that in about half of my trials, when we're ready to go at 9:00 o'clock on the second day, one juror is not here because they didn't anticipate traffic, so please factor that in so we can start right at 9:00 o'clock.

As I mentioned, we've got a schedule and a time limit in the case, so we're going to try and stay right on schedule so we finish it on time.

Please also remember not to talk about the case or do any research about it, and we will plan to see you at 9:00 in the morning.

We'll excuse the jury. Thank you.

(Jury not present.)

THE COURT: All right, counsel. For your information, plaintiff used 1 hour and 5 minutes, and defendants used 1 hour

and 9 minutes.

I've got another hearing that I need to start in a couple of minutes. Are there any urgent matters that we need to take up?

MR. LOPEZ: Well, I'm not sure it's urgent, but in his opening statement, he made the statement about Dr. Henry getting a patient brochure and whether or not he shared it with Mrs. Hyde. I mean, he just turned this into a warnings case.

I mean, he said that right at the end when he was going through the patient brochure. And he went through every single complication that's relevant in this case. Now the jury's wondering, well, she must have got this from Dr. Henry.

I mean, this has now become a warnings case. If it is, then we ought to be able to put on, you know, our evidence of all that. I'm just putting it out there, Judge.

THE COURT: Mr. Lopez, how is that different from what I described this morning, that they're entitled to tell doctors about -- or to tell the jury about what risks doctors were advised of and you're entitled to tell the jury of what risks doctors weren't advised of so the jury can decide if this product was reasonably safe?

MR. LOPEZ: He went beyond -- he stepped over the line. He talked about Dr. -- he talked about Dr. Henry sharing that with Mrs. Hyde. That becomes a warning now that goes to Mrs. Hyde and whether or not Dr. Henry provided that.

I just -- I mean, I understand this line that we're dealing with, Judge. We're dealing with it, too, so I appreciate it. But I have to be mindful as I hear the evidence, is it becoming an unfair advantage that they get to talk about certain things and we don't.

So, I mean, you said it this morning, it's a struggle. And I don't know where that -- it's a blurred line. But I think he crossed it in his opening. I'm just -- not that we have to resolve it now.

THE COURT: Well, therefore, what?

MR. LOPEZ: Well, I mean, therefore, we will look at the way maybe some of the evidence has been ruled on with respect to that to see if we can convince you that maybe you ought to let some of that in, if that's what's going to happen at trial.

THE COURT: Well, you're certainly free to raise that later on.

MR. LOPEZ: I understand.

THE COURT: Okay, counsel. Please be here at 8:30 in the morning, and we'll plan to get started then and deal with any issues. And we'll get the jury right in here at 9:00.

Thank you.

(Proceedings concluded at 4:29 p.m.)

C E R T I F I C A T E

I, JENNIFER A. PANCRATZ, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control.

DATED at Phoenix, Arizona, this 19th day of September, 2018.

s/Jennifer A. Pancratz
Jennifer A. Pancratz, RMR, CRR, FCRR, CRC